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Delegations will find in the Annex to this document a consolidated text for the Articles of the proposed Regulation mentioned above prepared by the Latvian Presidency with a view to the meeting of the Council (EPSCO) on 19 June 2015.

At its meeting on 10 June 2015, the Permanent Representatives Committee agreed to forward the text in the Annex to this Note to the Council with a view to reaching a Partial General Approach (excluding recitals).

New text compared to the Commission proposal is written in ***bold italics***. Deletions are marked by ~~strikethrough~~.

Proposal for a  
**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**  
on *in vitro* diagnostic medical devices

**Chapter I**  
**Scope and definitions**

*Article 1*

*Scope*

1. This Regulation ~~establishes~~ ***lays down*** rules ~~to be complied with by *in vitro* diagnostic medical devices and accessories to *in vitro* diagnostic medical devices that are placed~~ ***concerning the placing on the market, making available*** on the market or ***putting*** into service of ***in vitro diagnostic medical devices and accessories to in vitro diagnostic medical devices for human use*** in the Union ~~for human use~~. ***This regulation also applies to performance studies on in vitro diagnostic medical devices conducted in the Union.***
- 1a.*** For the purposes of this Regulation, *in vitro* diagnostic medical devices and accessories to *in vitro* diagnostic medical devices shall hereinafter be referred to as 'devices'.
2. This Regulation shall not apply to:
  - (a) products for general laboratory use ***or research-use only products***, unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for *in vitro* diagnostic examination;
  - (b) invasive sampling devices or those which are directly applied to the human body for the purpose of obtaining a specimen;
  - (c) ~~higher metrological order~~ ***internationally certified*** reference materials;;
  - (d) ***materials used for external quality assessment schemes***;.

3. Any device which, when placed on the market or *put into service and* used in accordance with the manufacturer's instructions incorporates as an integral part a medical device as defined in Article 2 of Regulation (EU) [Ref. of future Regulation on medical devices] on medical devices ~~without being an *in vitro* diagnostic medical device~~, shall be governed by this Regulation, ~~provided that the principal intended purpose of the combination is that of an *in vitro* diagnostic medical device referred to in Article 2(2) of this Regulation~~. The relevant ~~general safety and performance~~ requirements set out in Annex I to *of* Regulation (EU) [Ref. of future Regulation on medical devices] shall apply as far as the safety and performance ~~of to~~ the medical device part ~~that is not an *in vitro* diagnostic medical device~~ are concerned.
4. This Regulation is a specific Union legislation within the meaning of Article 1(4) of Directive 2004/108/EC ~~and within the meaning of Article 3 of Directive 2006/42/EC~~.
5. This Regulation shall not affect the application of Council Directive ~~96/29/Euratom~~, nor of Council Directive ~~97/43~~ **2013/59/Euratom**.
6. This Regulation shall not affect national laws ~~which require~~ *concerning the organisation, delivery or financing of health services and medical care, such as that the requirement that certain devices may only be supplied on a medical prescription, the requirement that only certain health professionals or health care institutions may dispense or apply certain devices or that their application must be accompanied by specific professional counselling*.
- 6a. *This Regulation shall be without prejudice to national laws regarding public access to official documents and regarding freedom of the press and freedom of expression in other media.*
7. ~~References to a Member State in this Regulation shall be understood as also including any other country with which the Union has concluded an agreement which confers on that country the same status as a Member State for the purpose of application of this Regulation.~~

## Article 2

### Definitions

For the purposes of this Regulation, the following definitions shall apply:

Definitions related to devices:

- (1) ‘medical device’ means any instrument, apparatus, appliance, software, implant, reagent material or other article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purposes of:
- diagnosis, prevention, monitoring, treatment or alleviation of disease,
  - diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability,
  - investigation, replacement or modification of the anatomy or of a physiological **or pathological** process or state,
  - ~~control or support of conception,~~
  - ~~disinfection or sterilisation of any of the above mentioned products.~~
  - **providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations.**

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

***Products specifically intended for the cleaning, disinfection or sterilisation of medical devices and devices for the purpose of control or support of conception shall be considered medical devices.***

- (2) ‘*in vitro* diagnostic medical device’ means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

- concerning a physiological or pathological **process or** state;
- concerning a congenital abnormality;
- concerning the predisposition to a medical condition or a disease;
- to determine the safety and compatibility with potential recipients;
- to predict treatment response or reactions;
- to define or monitor therapeutic measures.

Specimen receptacles are considered to be *in vitro* diagnostic medical devices. For the purposes of this Regulation, ‘specimen receptacle’ means devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of *in vitro* diagnostic examination.

- (3) 'accessory to an *in vitro* diagnostic medical device' means an article which, whilst not being an *in vitro* diagnostic medical device, is intended by its manufacturer to be used together with one or several particular *in vitro* diagnostic medical device(s) to specifically enable ~~or assist~~ the *in vitro* diagnostic medical device(s) to be used in accordance with its/their intended purpose(s);
- (4) 'device for self-testing' means any device intended by the manufacturer to be **able to be** used by lay persons;
- (5) 'device for near-patient testing' means any device that is not intended for self-testing but is intended to perform testing outside a laboratory environment, generally near to, or at the side of, the patient;

(6) 'companion diagnostic' means a device *which is essential for the safe and effective use of a corresponding medicinal product to:*

- *identify patients who are most likely to benefit from the medicinal product, or;*
- *identify patients likely to be at increased risk for serious adverse reactions as a result of treatment with the medicinal product, or;*
- *monitor response to treatment by the medicinal product for the purpose of adjusting treatment to achieve improved safety or effectiveness;*

~~specifically intended to select patients with a previously diagnosed condition or predisposition as eligible for a targeted therapy;~~

(7) 'generic device group' means a set of devices having the same or similar intended purposes or commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;

(8) 'single-use device' means a device that is intended to be used ~~on an individual patient~~ during a single procedure;

~~The single procedure may involve several uses or prolonged use on the same patient.~~

**(8a) 'falsified medical device' means any device with a false presentation of its identity, and/or of its source and/or its CE marking certificates or documents relating to CE marking procedures. This definition does not include unintentional non-compliance and is without prejudice to infringements of intellectual property rights;**

**(8a) 'kit' means a set of components that are packaged together and intended to be used to perform a specific in vitro diagnostic examination, or a part thereof;**

(9) 'intended purpose' means the use for which the device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements;

- (10) 'label' means the written, printed, or graphic information appearing either on the device itself, or on the packaging of each unit, or on the packaging of multiple devices;
- (11) 'instructions for use' means the information provided by the manufacturer to inform the user of the device's intended purpose and proper use and of any precautions to be taken;
- (12) 'Unique Device Identification' ('UDI') means a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market;

Definitions related to the making available of devices:

- (13) 'making available on the market' means any supply of a device, other than a device for performance evaluation, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;
- (14) 'placing on the market' means the first making available of a device, other than a device for performance evaluation, on the Union market;
- (15) 'putting into service' means the stage at which a device, other than a device for performance evaluation, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose;
- (15a) 'safety' means the absence of unacceptable risks, when using the device according to the manufacturer's instructions for use;***
- (15b) 'benefit-risk determination' means the integration of all assessments of benefit and risk of possible relevance for the use of the device for the intended purpose, when used in accordance with the instructions of use;***

Definitions related to economic operators, users and specific processes:

- (16) ‘manufacturer’ means the natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under his name or trademark, ***regardless of whether these operations are carried out by that person himself or on his behalf by a third party.***

For the purposes of the definition of manufacturer, fully refurbishing is defined as the complete rebuilding of a device already placed on the market or put into service, or the making of a new device from used devices, to bring it in conformity with this Regulation, combined with the assignment of a new lifetime to the refurbished device;

***(16a) ‘compatibility’ is the ability of a medical device, including software, when used together with one or more other devices in accordance with its intended purpose, to:***

- ***perform without losing or compromising the ability to perform as intended, and/or***
- ***integrate and/or operate without the need for modification or adaption of any part of the combined devices, and/or***
- ***be used together without conflict/interference or adverse reaction.***

***(16b) ‘interoperability’ is the ability of two or more medical devices, including software, from the same manufacturer or from different manufacturers, to***

- ***exchange information and use the information that has been exchanged for correct execution of specified function without changing the content of the data, and/or***
- ***enable the communication of one or more devices, and/or***
- ***enable one or more devices to work together as intended.***

- (17) 'authorised representative' means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, ***located outside the European Union***, to act on his behalf in relation to specified tasks with regard to the latter's obligations under this Regulation;



- (18) 'importer' means any natural or legal person established within the Union who places a device from a third country on the Union market;
- (19) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a device available on the market;
- (20) 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;
- (21) 'health institution' means an organisation whose primary purpose is the care or treatment of patients or the promotion of public health;
- (22) 'user' means any healthcare professional or lay person who uses a device;
- (23) 'lay person' means an individual who does not have formal education in a relevant field of healthcare or medical discipline;

Definitions related to conformity assessment:

- (24) 'conformity assessment' means the process demonstrating whether the requirements of this Regulation relating to a device have been fulfilled;
- (25) 'conformity assessment body' means a body that performs third-party conformity assessment activities including calibration, testing, certification and inspection;
- (26) 'notified body' means a conformity assessment body designated in accordance with this Regulation;
- (27) 'CE marking of conformity' or 'CE marking' means a marking by which the manufacturer indicates that the device is in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonisation legislation providing for its affixing;

Definitions related to clinical evidence:

- (28) 'clinical evidence' means the ***clinical data and performance evaluation results pertaining to a device of sufficient amount and quality to allow a qualified assessment of whether the device achieves the intended clinical benefit(s) and safety, when used*** ~~information that supports the scientific validity and performance for the use of a device as intended by the manufacturer;~~
- (29) 'scientific validity of an analyte' means the association of an analyte to a clinical condition or a physiological state;
- (30) 'performance of a device' means the ability of a device to achieve its intended purpose as claimed by the manufacturer. It consists of the analytical and, where applicable, the clinical performance supporting the intended purpose of the device;
- (31) 'analytical performance' means the ability of a device to correctly detect or measure a particular analyte;
- (32) 'clinical performance' means the ability of a device to yield results that are correlated with a particular clinical condition or a physiological state in accordance with the target population and intended user;
- (33) '~~clinical~~ performance study' means a study undertaken to establish or confirm the clinical performance of a device;
- (34) 'clinical performance study ***plan protocol***' means the document(s) setting out the rationale, objectives, design and proposed analysis, methodology, monitoring, conduct and record-keeping of the clinical performance study;
- (35) 'performance evaluation' means the assessment and analysis of data to establish or verify the ***scientific validity***, the analytical and, where applicable, the clinical performance of a device;

- (36) 'device for performance evaluation' means a device intended by the manufacturer to be subject to one or more performance evaluation studies in laboratories for medical analyses or in other appropriate environments outside the manufacturer's own premises. Devices intended to be used for research purposes, without any medical objective, are not regarded as devices for performance evaluation;
- (37) 'interventional clinical performance study' means a clinical performance study where the test results may influence patient management decisions and/or may be used to guide treatment;
- (37a) 'subject' means an individual who participates in a performance study either as recipient of a device for performance evaluation or as control;**
- (38) 'diagnostic specificity' means the ability of a device to recognize the absence of a target marker associated with a particular disease or condition;
- (39) 'diagnostic sensitivity' means the ability of a device to identify the presence of a target marker associated with a particular disease or condition;
- (40) 'predictive value' means the probability that a person with a positive device test result has a given condition under investigation, or that a person with a negative device test result does not have a given condition;
- (41) 'positive predictive value' means the ability of a device to separate true positive results from false positive results for a given attribute in a given population;
- (42) 'negative predictive value' means the ability of a device to separate true negative results from false negative results for a given attribute in a given population;

- (43) 'likelihood ratio' means the likelihood that a given result would be expected in an individual with the target clinical condition or physiological state compared to the likelihood that the same result would be expected in an individual without that clinical condition or physiological state;
- (44) 'calibrators and control materials' means any substance, material or article intended by the manufacturer either to establish measurement relationships or to verify the performance characteristics of a device in conjunction with the intended purpose of that device;
- (45) 'sponsor' means any individual, company, institution or organisation which takes responsibility for the initiation ~~and~~ **for the** management **and for setting up the financing** of a ~~the clinical~~ performance study;
- (45a) 'informed consent' means a subject's free and voluntary expression of his or her willingness to participate in a particular clinical investigation, after having been informed of all aspects of the performance evaluation study that are relevant to the subject's decision to participate or, in case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in the performance evaluation study;**
- (45b) 'Ethics committee' means an independent body established in a Member State in accordance with the law of that Member State and empowered to give opinions for the purposes of this Regulation, taking into account the views of laypersons, in particular patients or patients' organisations;**
- (46) 'adverse event' means any untoward medical occurrence, **inappropriate patient management decision**, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons in the context of a ~~clinical~~ performance study, whether or not related to the device for performance **study** evaluation;

- (47) 'serious adverse event' means any adverse event that led to any of the following:
- ***a patient management decision resulting in an imminent life-threatening situation to the individual being tested, or in the death of the individual's offspring,***
  - death,
  - serious deterioration in the health of the ~~subject~~ ***individual being tested or the recipient of tested donations or materials,*** that resulted in any of the following:
    - (i) life-threatening illness or injury,
    - (ii) permanent impairment of a body structure or a body function,
    - (iii) hospitalisation or extending the duration of hospitalisation,
    - (iv) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,
    - (v) *chronic disease,***
  - foetal distress, foetal death or a congenital abnormality or birth defect.
- (48) 'device deficiency' means any inadequacy in the identity, quality, durability, reliability, safety or performance of a device for performance evaluation, including malfunction, use errors or inadequacy in the information supplied by the manufacturer;

Definitions related to vigilance and market surveillance:

***(48a) 'Market Surveillance' means all activities carried out by the manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from their devices placed on the market, made available or put into service for the purpose of identifying any need to immediately apply any necessary, corrective or preventive actions;***

(49) 'recall' means any measure aimed at achieving the return of a device that has already been made available to the end user;

- (50) 'withdrawal' means any measure aimed at preventing a device in the supply chain from further being made available on the market;
- (51) 'incident' means any malfunction or deterioration in the characteristics or performance of a device made available on the market ***including use-error due to ergonomic features***, any inadequacy in the information supplied by the manufacturer and any ~~unexpected undesirable effect~~ ***harm as a consequence of the medical decision, action taken or not taken on the basis of information or result(s) provided by the device;***
- (52) 'serious incident' means any incident that directly or indirectly led, might have led or might lead to any of the following:
- death of a patient, user or other person,
  - temporary or permanent serious deterioration of the patient's, user's or other person's state of health,
  - serious public health threat;
- (52a) 'serious public health threat' means any event type which results in imminent risk of death, serious deterioration in state of health, or serious illness that may requires prompt remedial action;***
- (53) 'corrective action' means action taken to eliminate the cause of a potential or real non-conformity or other undesirable situation;
- (54) 'field safety corrective action' means corrective action taken by the manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market;
- (55) 'field safety notice' means the communication sent by the manufacturer to users or customers in relation to a field safety corrective action;

- (56) 'market surveillance' means the activities carried out and measures taken by public authorities to **check and** ensure that ~~products~~ **devices** comply with the requirements set out in the relevant Union harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection;

Definitions related to standards and other technical specifications:

- (57) 'harmonised standard' means a European standard as defined in Article 2(1)(c) of Regulation (EU) No [Ref. of future Regulation on European standardisation];
- (58) 'common ~~technical~~ specifications' means a document other than a standard that prescribes technical requirements that provide a means to comply with the legal obligations applicable to a device, process or system.

### *Article 3*

#### *Regulatory status of products*

1. ~~The~~ ***Without prejudice to Article 2(2) of Directive 2001/83, at a duly substantiated request of a Member State, the Commission may shall, at the request of a Member State or on its own initiative after consulting with the MDCG,*** by means of implementing acts, determine whether or not a specific product, or category or group of products, falls within the definitions of an *in vitro* diagnostic medical devices or of an accessory to an *in vitro* diagnostic medical device. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).
- 1a. The Commission may also, on its own initiative, after consulting the MDCG, decide, by means of implementing acts, on the issues referred to in paragraph 1.***

2. The Commission shall ensure the sharing of expertise between Member States, in the fields of *in vitro* diagnostic medical devices, medical devices, medicinal products, human tissues and cells, cosmetics, biocides, food and, if necessary, other products in order to determine the appropriate regulatory status of a product, or category or group of products.



## Chapter II

# Making available of devices, obligations of economic operators, CE marking, free movement

### Article 4

#### *Placing on the market and putting into service*

1. A device may be placed on the market or put into service only if it complies with this Regulation when duly supplied and properly installed, maintained and used in accordance with its intended purpose.
2. A device shall meet the general safety and performance requirements which apply to it, taking into account its intended purpose. General safety and performance requirements are set out in Annex I.
3. Demonstration of conformity with the general safety and performance requirements shall ~~be based on~~ **include a clinical evidence performance evaluation** in accordance with Article 47.
4. Devices that are manufactured and used within ~~a single~~ health institutions shall be considered as being put into service.
5. With the exception of ~~Article 59(4)~~ **the relevant general safety and performance requirements set out in Annex I**, the requirements of this Regulation shall not apply to devices ~~classified as class A, B and C, in accordance with the rules set out in Annex VII, and~~ manufactured and used only within ~~a single~~ health institutions **established in the Union**, provided **that the following conditions are met:**
  - (aa) **the device is not transferred to another legal entity**
  - (a) manufacture and use **of the device** occur solely under ~~the health institution's~~ **appropriate** ~~single~~ quality management systems, ~~and~~

- (b) *the laboratory of the health institution is compliant with standard EN ISO 15189 or any other equivalent recognised standard and where applicable national provisions, including national provisions regarding accreditation.*
- (c) *the health institution establishes in its documentation that it has given due consideration as to whether the target patient group's specific needs cannot be met or cannot be met at the appropriate level of performance by an equivalent device available on the market;*
- (d) *the health institution provides information on annual basis on the use of such devices to their competent authority, which shall include a justification of their manufacturing, modification and use;*
- (e) *the health institution draws up a declaration, that it shall make publicly available including:*
- *the name and address of the manufacturing health institution;*
  - *the details necessary to identify the devices;*
  - *a declaration that the devices meet the general safety and performance requirements set out in Annex I of this Regulation and, where applicable, information on which requirements are not fully met with reasoned justification,*
- (f) *as regards devices classified as class C and D in accordance with the rules set out in Annex VII, the health institution draws up documentation, allowing an understanding of the manufacturing facility, the manufacturing process, the design and performance data of the devices, including the intended purpose, sufficiently detailed to enable the competent authority to ascertain that the general safety and performance requirements set out in Annex I of this Regulation are met; Member States may apply this provision also to devices classified as class A and B in accordance with the rules set out in Annex VII;*
- (g) *the health institution takes all necessary measures to ensure that all devices are manufactured in accordance with the documentation referred to in the previous subparagraph, and*

***(h) the health institution reviews experience gained from clinical use of the devices and takes all necessary corrective actions.***

Member States may require that the health institutions submit to the competent authority ~~a list of any further relevant information about~~ such devices which have been manufactured and used on their territory. ***Member States shall retain the right to restrict the manufacture and use of any specific type of such devices and may make the manufacture and use of the devices concerned subject to further safety requirements and shall be permitted access to inspect the activities of the health institutions.***

~~Devices classified as class D in accordance with the rules set out in Annex VII, even if manufactured and used within a single health institution, shall comply with the requirements of this Regulation. However, the provisions regarding CE marking set out in Article 16 and the obligations referred to in Articles 21 to 25 shall not apply to those devices.~~

***These provisions do not apply to devices which are manufactured on an industrial scale and which are used within the framework of a commercial diagnostic service.***

6. The Commission ~~may adopt implementing acts to ensure the uniform application of Annex I. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3)~~ shall be empowered to adopt delegated acts in accordance with Article 85, amending or supplementing, in the light of technical progress and considering the intended users or patients, the general safety and performance requirements set out in Annex I, including the information supplied by the manufacturer.

#### *Article 5*

##### *Distance sales*

1. A device offered by means of information society services as defined in Article 1(2) of Directive 98/34/EC to a natural or legal person established in the Union shall comply with this Regulation ~~at the latest~~ when the device is placed on the market.

2. Without prejudice to national legislation regarding the exercise of the medical profession, a device that is not placed on the market but used in the context of a commercial activity, ***whether in return for payment or free of charge***, for the provision of a diagnostic or therapeutic service offered by means of information society services as defined in Article 1(2) of Directive 98/34/EC or by other means of communication, ***directly or through intermediaries***, to a natural or legal person established in the Union shall comply with this Regulation.
3. ***Upon request by a competent authority, the natural or legal person offering a device in accordance with paragraph 1 or providing a service in accordance with paragraph 2 shall make available a copy of the EU declaration of conformity of the device concerned.***
4. ***A Member State may on grounds of protection of public health, require a provider of information society services as defined in Article 1(2) of Directive 98/34/EC to cease its activity.***

#### *Article 6*

##### *Harmonised standards*

1. Devices which are in conformity with the relevant harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the requirements of this Regulation covered by those standards or parts thereof.
2. The first subparagraph shall also apply to system or process requirements to be fulfilled by economic operators or sponsors in accordance with this Regulation, including those related to the quality management system, risk management, the post-market surveillance plan, clinical performance studies, clinical evidence or post-market ***performance*** follow-up.

3. Reference to harmonised standards also includes the monographs of the European Pharmacopoeia adopted in accordance with the Convention on the Elaboration of a European Pharmacopoeia, ***the references of which have been published in the Official Journal of the European Union.***

#### *Article 7*

##### *Common specifications*

1. Where no harmonised standards exist or where relevant harmonised standards are not sufficient, the Commission, ***after having consulted the MDCG, shall be empowered to may*** adopt common ~~technical~~ specifications (***CTSCS***) in respect of the general safety and performance requirements set out in Annex I, the technical documentation set out in Annex II ~~or~~, the ~~clinical evidence~~ ***performance evaluation*** and post-market ***performance clinical*** follow-up set out in Annex XII ***or the requirements regarding clinical-performance studies set out in Annex XIII.*** The ***CTSCS*** shall be adopted by means of implementing acts in accordance with the examination procedure referred to in Article 84(3).
2. Devices which are in conformity with the ~~ETS~~ ***CS*** referred to in paragraph 1 shall be presumed to be in conformity with the requirements of this Regulation covered by those ~~ETS~~ ***CS*** or parts thereof.
3. Manufacturers shall comply with the ~~ETS~~ ***CS*** unless they can duly justify that they have adopted solutions ensuring a level of safety and performance that is at least equivalent thereto.

## Article 8

### *General obligations of the manufacturer*

1. When placing their devices on the market or putting them into service, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements of this Regulation.

**1a. *Manufacturers shall establish, execute, maintain and document a system for Risk Management as described in Section I.2 in Annex I.***

**1c. *Manufacturers shall conduct a performance evaluation in accordance with the principles set out in Article 47 and Annex XII, including post-market performance follow-up.***

2. Manufacturers shall draw up ***and keep up to date*** the technical documentation which shall allow assessment of the conformity of the device with the requirements of this Regulation. The technical documentation shall include the elements set out in Annex II.

The Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing, in the light of technical progress, the elements in the technical documentation set out in Annex II.

3. Where compliance of a device with the applicable requirements has been demonstrated following the applicable conformity assessment procedure, manufacturers of devices, other than devices for performance evaluation, shall draw up an EU declaration of conformity in accordance with Article 15, and affix the CE marking of conformity in accordance with Article 16.

**3a. *Manufacturers shall comply with the obligations related to the UDI system referred to in Articles 22 and with the registration obligations referred to in Article 23.***

4. Manufacturers shall keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate including any **amendments and** supplements, issued in accordance with Article 43, available to the competent authorities for a period of at least five years after the last device covered by the declaration of conformity has been placed on the market.

~~Where the technical documentation is voluminous or held in different locations, the manufacturer shall provide, Upon request by a competent authority, the manufacturer shall provide the full technical documentation or a summary technical documentation (STED) and grant access to the full technical documentation upon as indicated in the request.~~

***Manufacturer with registered place of business outside the Union, to allow the authorised representative to fulfil the tasks mentioned in Article 9, paragraph 3 shall ensure that the authorised representative has permanently available to the necessary documentation.***

5. Manufacturers shall ensure that procedures are in place to keep series production in conformity with the requirements of this Regulation. Changes in product design or characteristics and changes in the harmonised standards or ~~ETSCS~~ by reference to which conformity of a product is declared shall be adequately taken into account ***in a timely manner***. Proportionate to the risk class and the type of device, manufacturers of devices, other than devices for performance evaluation, shall ~~institute~~ ***establish, document, implement, maintain, and keep up to date and continually improve*** a quality management system that shall ~~address at least~~ ***ensure compliance with this regulation in the most effective manner***.

***The QMS consists of all parts and components of a manufacturer's organisation dealing with the quality of processes, procedures and devices. It is managing the structure, responsibilities, procedures, processes and management resources to implement the needed principles and actions to achieve compliance with the provisions of this regulation.***

*The quality management system shall address at least the following aspects:*

- (aa) a strategy for regulatory compliance, including compliance with conformity assessment procedures and management change;*
- (ab) identification of applicable general safety and performance requirements and exploration of options to address these;*
  - (a) the responsibility of the management;
  - (b) resource management, including selection and control of suppliers and sub-contractors;
- (ba) risk management according to section I. 2 of Annex I;*
- (bc) clinical evaluation, according to Article 49 and Annex XIII, including post-market clinical follow-up;*
- (c) product realisation, *including planning, design, development, production and service provision;*
  - (ca) control of the UDI-Code assignments to all relevant devices and ensuring consistency and validity of information provided according to Article 25;*
  - (cb) setting-up, implement and maintain a systematic post-market surveillance plan according to Article 58b;*
  - (cc) handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders;*
  - (cd) processes for reporting of serious incidents and field safety corrective actions in the context of vigilance;*
  - (ce) management of corrective and preventive actions and verification of their effectiveness;*
- (d) processes for monitoring and measurement of output, data analysis and product improvement.



6. Proportionate to the risk class and the type of device, manufacturers of devices shall ~~institute~~ **implement** and keep up to date ~~the~~ a systematic procedure to collect and review experience gained from their devices placed on the market or put into service and to apply any necessary corrective action, hereinafter referred to as ‘post-market surveillance plan’ **system referred to in Article 58a**. ~~The post-market surveillance plan shall set out the process for collecting, recording and investigating complaints and reports from healthcare professionals, patients or users on suspected incidents related to a device, keeping a register of non-conforming products and product recalls or withdrawals, and if deemed appropriate due to the nature of the device, sample testing of marketed devices. Part of the post-market surveillance plan shall be a plan for post-market performance follow-up in accordance with Part B of Annex XII. Where post-market performance follow-up is not deemed necessary, this shall be duly justified and documented in the post-market surveillance plan.~~

~~If in the course of the post-market surveillance a need for corrective action is identified, the manufacturer shall implement the appropriate measures.~~

7. Manufacturers shall ensure that the device is accompanied by the information to be supplied in accordance with Section 17 of Annex I in an official Union language ~~which can be easily understood by the intended user~~ **determined by the concerned Member State**. The language(s) of the information to be supplied by the manufacturer may be determined by the law of the Member State where the device is made available to the user. **The particulars on the label shall be easily legible, clearly comprehensible and indelible.**

For devices for self-testing or near-patient-testing, the information supplied in accordance with Section 17 of Annex I shall be provided in the language(s) of the Member State where the device reaches its intended user.

8. Manufacturers who consider or have reason to believe that a device which they have placed on the market *or put into service* is not in conformity with this Regulation shall immediately take the necessary corrective action to bring that product into conformity, withdraw it or recall it, as appropriate. They shall inform *accordingly* the distributors and, where applicable, the authorised representative ~~accordingly~~ *and the importers. Where the device presents a serious risk, manufacturers shall immediately inform the competent authorities of the Member States in which they made the device available and, where applicable, the notified body that issued a certificate for the device in accordance with Article 43, in particular, of the non-compliance and of any corrective action taken.*

*8a. Manufacturers shall have a system for reporting of incidents and field safety corrective actions as described in Article 59.*

9. Manufacturers shall, ~~in response to a reasoned~~ *upon* request from a competent authority, provide it with all the information and documentation necessary to demonstrate the conformity of the device, in an official Union language ~~which can be easily understood by that authority~~ *determined by the Member State concerned. They* *The competent authority where the manufacturer has his registered place of business may require that the manufacturer provide samples of the device free of charge or, where impracticable, grant access to the device. Manufacturers shall cooperate with that a competent authority, at its request, on any corrective action taken to eliminate the risks posed by devices which they have placed on the market or put into service.*

*If the manufacturer fails to cooperate or the information and documentation provided is incomplete or incorrect, the competent authority may suspend the involved device until its demonstration of conformity to the essential requirements.*

10. Where manufacturers have their devices designed and manufactured by another legal or natural person the information on the identity of that person shall be part of the information to be submitted in accordance with Article 23.

**11. Natural or legal persons may claim compensation for damage caused by a defective device in accordance with applicable Union and national law.**

**To this end, manufacturers shall consider taking out appropriate insurance or arranging for an equivalent financial guarantee, to cover the costs associated with defective devices.**

#### Article 9

##### Authorised representative

1. **Where the A manufacturer of a device is not established in any Member State, that is the device may only be placed on the Union market, or bears the CE marking without being placed on the Union market, who does not have a registered place of business in a Member State or does not carry out relevant activities at a registered place of business in a Member State, shall if the manufacturer designates a single authorised representative.**
2. The designation shall **constitute the authorised representative's mandate, it shall** be valid only when accepted in writing by the authorised representative and shall be effective at least for all devices of the same generic device group.
3. The authorised representative shall perform the tasks specified in the mandate agreed between the manufacturer and the authorised representative. **The authorised representative shall provide a copy of the mandate to the competent authority.**

The mandate shall allow and require the authorised representative to perform at least the following tasks in relation to the devices that it covers:

- (aa) **verify that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;**
- (a) keep **a copy of** the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate including any supplement **amendments and supplements** issued in accordance with Article 43 at the disposal of competent authorities for the period referred to in Article 8(4);

- (ab) *comply with the registration obligations laid down in Article 23a(1), (4) and (5);*
- (b) in response to a reasoned request from a competent authority, provide that competent authority with all the information and documentation necessary to demonstrate the conformity of a device *in a language determined by Member State concerned;*
- (ca) *forward to the manufacturer any request by a competent authority where he has his registered place of business for samples, or access to a device and verify that the competent authority receives the samples or gets access to the device;*
- (c) cooperate with the competent authorities on any corrective action taken to eliminate the risks posed by devices;
- (d) immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated;
- (e) terminate the mandate if the manufacturer acts contrary to his obligations under this Regulation.

~~To allow the authorised representative to fulfil the tasks mentioned in this paragraph, the manufacturer shall at least ensure that the authorised representative has permanent immediate access to the necessary documentation in one of the official Union languages.~~

4. The mandate referred to in paragraph 3 shall not include the delegation of the manufacturer's obligations laid down in Article 8(1), (2), **(3)**, **(3a)**, (5), (6), (7) and (8).

**4a. Without prejudice to paragraph 4, where the manufacturer is not established in any Member State, and has not complied with the obligations laid down in Article 8, the authorised representative shall be legally liable for defective devices in accordance with Article 8(13).**

5. An authorised representative who terminates the mandate on the grounds referred to in point (e) of paragraph 3 shall immediately inform the competent authority of the Member State in which he is established and, where applicable, the notified body that was involved in the conformity assessment for the device of the termination of the mandate and the reasons therefor.
6. Any reference in this Regulation to the competent authority of the Member State where the manufacturer has his registered place of business shall be understood as a reference to the competent authority of the Member State where the authorised representative, designated by a manufacturer referred to in paragraph 1, has his registered place of business.

#### *Article 10*

##### *Change of authorised representative*

The modalities of a change of authorised representative shall be clearly defined in an agreement between the manufacturer, **where practicable**, the outgoing authorised representative and the incoming authorised representative. This agreement shall address at least the following aspects:

- (a) the date of termination of the mandate with the outgoing authorised representative and date of beginning of the mandate with the incoming authorised representative;
- (b) the date until which the outgoing authorised representative may be indicated in the information supplied by the manufacturer, including any promotional material;
- (c) the transfer of documents, including confidentiality aspects and property rights;
- (d) the obligation of the outgoing authorised representative after the end of the mandate to forward to the manufacturer or to the incoming authorised representative any complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device for which he had been designated as authorised representative.

## Article 11

### General obligations of importers

1. Importers shall place on the Union market only devices that are in conformity with this Regulation.
2. ~~Before placing~~ ***In order to place*** a device on the market importers shall ~~ensure~~ ***verify*** the following:
  - (a) ~~that the appropriate conformity assessment procedure has been carried out by the manufacturer~~ ***device has been CE marked and that the declaration of conformity of the device has been drawn up;***
  - (b) that an authorised representative in accordance with Article 9 has been designated by the manufacturer;
  - (c) ~~that the EU declaration of conformity and the technical documentation has been drawn up by the manufacturer;~~
  - (d) ~~that the device bears the required CE marking of conformity;~~
  - (e) that the device is labelled in accordance with this Regulation and accompanied by the required instructions for use ~~and EU declaration of conformity;~~
  - (f) that, where applicable, a Unique Device Identification has been assigned by the manufacturer in accordance with Article 22;

Where an importer considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, he shall not place the device on the market until it has been brought into conformity. ~~Where the device presents a risk, the importer~~ ***and*** shall inform the manufacturer his authorised representative. ~~to that effect, as well as~~ ***Where the importer consider or has reason to believe that the device presents a serious risk or is falsified, he shall also inform*** the competent authority of the Member State in which he is established.

3. Importers shall indicate their name, registered trade name or registered trade mark and the address of their registered place of business at which they can be contacted and their location can be established on the device or on its packaging or in a document accompanying the device. They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer.
4. Importers shall ~~ensure~~ **verify** that the device is registered in the electronic system in accordance with Article 232b(2), **and shall add their details to that registration. Importers shall also verify that the registration includes details on the authorised representative and, if appropriate, inform the authorised representative or the manufacturer.**
5. Importers shall ensure that, while a device is under their responsibility, storage or transport conditions do not jeopardise its compliance with the general safety and performance requirements set out in Annex I **and shall comply with the conditions set by the manufacturer, where available.**
6. ~~When deemed appropriate with regard to the risks presented by a device, importers shall, in order to protect the health and safety of patients and users, carry out sample testing of marketed products, investigate complaints and~~ **Importers shall** keep a register of complaints, of non-conforming products and of product recalls and withdrawals, and ~~shall keep~~ **provide** the manufacturer, authorised representative and distributors ~~informed of such monitoring.~~ **with any information requested by them, in order to allow them to investigate complaints.**

7. Importers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately inform the manufacturer and his authorised representative. ~~and, if appropriate, take~~ ***Importers shall co-operate with the manufacturer, his authorised representative and the competent authorities to ensure that*** the necessary corrective action to bring that device into conformity, withdraw or recall it ***is taken***. Where the device presents a ***serious*** risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available ~~and, if applicable, the notified body that issued a certificate in accordance with Article 43 for the device in question,~~ giving details, in particular, of the non-compliance and of any corrective action taken.
8. Importers who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device which they have placed on the market shall immediately forward this information to the manufacturer and his authorised representative.
9. Importers shall, for the period referred to in Article 8(4), keep a copy of the EU declaration of conformity ~~at the disposal of the market surveillance authorities and ensure that the technical documentation~~ and, if applicable, a copy of the relevant certificate including any supplement, issued in accordance with Article 43, ~~can be made available to those authorities, upon request. By written mandate, the importer and the authorised representative for the device in question may agree that this obligation is delegated to the authorised representative.~~
10. ~~Importers shall, in response to a request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of a product. This obligation shall be considered fulfilled when the authorised representative for the device in question provides the required information.~~ Importers shall cooperate with competent a national ***authorities*** authority, at its ~~their~~ request, on any action taken to eliminate the risks posed by ***devices*** ~~products~~ which they have placed on the market. ***Importers, upon request of a competent authority where the importer has his registered place of business, shall provide samples of the device free of charge or, where impracticable, grant access to the device.***



## Article 12

### General obligations of distributors

1. ~~When~~ ***In the context of their activities, when*** making a device available on the market, distributors shall act with due care in relation to the requirements applicable.
2. Before making a device available on the market distributors shall verify that the following requirements are met:
  - (a) the ~~device product bears the required CE marking of conformity~~ ***has been CE marked and that the declaration of conformity of the device has been drawn up;***
  - (b) the product is accompanied by the information to be supplied by the manufacturer in accordance with Article 8(7) ***and by the EU declaration of conformity;***
  - (c) ~~the manufacturer and, where applicable, the importer have complied with the requirements set out in Article 22 and Article 11(3) respectively.~~
  - (d) ***that, where applicable, a Unique Device Identification has been assigned by the manufacturer.***

***In order to meet the requirements referred to in subparagraphs (a) and (b) the distributor may apply a sampling method representative of products supplied by that distributor.***

Where a distributor considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, he shall not make the device available on the market until it has been brought into conformity. ~~Where the device presents a risk, the distributor shall~~ ***and*** inform the manufacturer and, where applicable, his authorised representative, and the importer ~~to that effect, as well as~~ ***Where the distributor consider or has reason to believe that the device presents a serious risk or is falsified, he shall also inform*** the competent authority of the Member State in which he is established.

3. Distributors shall ensure that, while a ***the*** device is under their responsibility, storage or transport conditions ~~do not jeopardise its compliance with the general safety and performance requirements set out in Annex I~~ ***comply with the conditions set by the manufacturer.***

4. Distributors who consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, his authorised representative and the importer ~~and make sure~~. ***Distributors shall co-operate with the manufacturer and, where applicable his authorised representative and the importer, and with any competent authorities to ensure that the necessary corrective action to bring that device into conformity, withdraw or recall it, if appropriate, is taken. Where the distributor considers or has reason to believe that the device presents a serious risk, he they shall also immediately inform the competent authorities of the Member States in which they he made the device available, and, where applicable, the notified body that issued a certificate for the device in accordance with Article 43, giving details, in particular, of the non-compliance and of any corrective action taken.***
  
5. Distributors who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device they have made available, shall immediately forward this information to the manufacturer and, where applicable, his authorised representative, ***They shall keep a register of complaints, of non-conforming products and of product recalls and withdrawals, and keep the manufacturer and, where available, the authorised representative informed of such monitoring and provide them with any information upon their request.***
  
6. Distributors shall, in response to a request from a competent authority, provide it with all the information and documentation ***that is at its disposal and is necessary*** to demonstrate the conformity of a device. This obligation shall be considered fulfilled when the authorised representative for the device in question, where applicable, provides the required information. Distributors shall cooperate with competent national authorities, at their request, on any action taken to eliminate the risks posed by devices which they have made available on the market. ***Distributors, upon request of a competent authority, shall provide free samples of the device or, where impracticable, grant access to the device.***

## Article 13

### *Person responsible for regulatory compliance*

1. Manufacturers shall have available within their organisation, at least one ~~qualified~~ person ***responsible for regulatory compliance activities*** who possesses expert knowledge in the field of in vitro diagnostic medical devices. The expert knowledge shall be demonstrated by either of the following qualifications:
  - (a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of ~~an~~ ***a course of study recognized as*** equivalent ~~course of study, in natural sciences,~~ ***by the Member States concerned, in*** medicine, pharmacy, engineering or another relevant discipline ***of sciences***, and at least two years of professional experience in regulatory affairs or in quality management systems relating to ~~in vitro diagnostic medical~~ devices;
  - (b) five years of professional experience in regulatory affairs ~~or~~ ***related to devices including experience*** in quality management systems relating to ~~in vitro diagnostic medical~~ devices.
  
- 1a. ***Micro and small enterprises within the meaning of Commission Recommendation 2003/361/EC are not required to have the person responsible for regulatory compliance within their organisation but shall have such person permanently and continuously at their disposal.***
  
2. The ~~qualified~~ person ***responsible for regulatory compliance activities*** shall at least be responsible for ensuring the following matters:
  - (a) that the conformity of the devices is appropriately ~~assessed~~ ***checked in accordance with the quality management system under which these devices are manufactured*** before a ~~batch~~ ***product*** is released;
  - (b) that the technical documentation and the declaration of conformity are drawn up and kept up-to-date;
  - (ca) ***that the post-market surveillance obligations according in accordance with Article 8(7) are complied with;***

- (c) that the reporting obligations in accordance with Articles 59 to 64 are fulfilled;
  - (d) in the case of devices for performance evaluation intended to be used in the context of interventional clinical performance studies or other clinical performance studies involving risks for the subjects, that the statement referred to in point 4.1 of Annex XIII is issued;
3. The ~~qualified~~ person **responsible for regulatory compliance** shall suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his duties.
4. Authorised representatives shall have ~~available within~~ **permanently and continuously at their disposal** ~~organisation~~ at least one ~~qualified~~ person **in charge for regulatory compliance activities** who possesses expert knowledge regarding the regulatory requirements for *in vitro* diagnostic medical devices in the Union. The expert knowledge shall be demonstrated by either of the following qualifications:
- (a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of ~~an~~ **a course of study recognized as equivalent by the Member States concerned** ~~course of study, in law, natural sciences, medicine,~~ pharmacy, engineering or another relevant ~~discipline~~ **sciences**, and at least two years of professional experience in regulatory affairs or in quality management systems relating to *in vitro* diagnostic medical devices;
  - (b) five years of professional experience in regulatory affairs or in quality management systems relating to *in vitro* diagnostic medical devices.

## Article 14

### *Cases in which obligations of manufacturers apply to importers, distributors or other persons*

1. A distributor, importer or other natural or legal person shall assume the obligations incumbent on manufacturers if he does any of the following:
  - (a) makes available on the market a device under his name, registered trade name or registered trade mark, ***except in cases where a distributor or importer enters into an agreement with a manufacturer whereby the manufacturer is identified as such on the label and is responsible for meeting the requirements placed on manufacturers in this Regulation;***
  - (b) changes the intended purpose of a device already placed on the market or put into service;
  - (c) modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected.

The first subparagraph shall not apply to any person who, while not considered a manufacturer as defined in number (16) of Article 2, assembles or adapts a device already on the market to its intended purpose for an individual patient.

2. For the purposes of point (c) of paragraph 1, the following shall not be considered to be a modification of a device that could affect its compliance with the applicable requirements:
  - (a) provision, including translation, of the information supplied by the manufacturer in accordance with Section 17 of Annex I relating to a device already placed on the market and of further information which is necessary in order to market the product in the relevant Member State;
  - (b) changes to the outer packaging of a device already placed on the market, including a change of pack size, if the repackaging is necessary in order to market the product in the relevant Member State and if it is carried out in such conditions that the original condition of the device cannot be affected by it. In the case of devices placed on the market in sterile condition, it shall be presumed that the original condition of the device is adversely affected if the package that shall ensure the sterile condition is opened, damaged or otherwise negatively affected by the repackaging.

3. A distributor or importer who carries out any of the activities mentioned in points (a) and (b) of paragraph 2 shall indicate the activity carried out together with his name, registered trade name or registered trade mark and the address at which he can be contacted and his location can be established on the device or, where ~~that is not possible~~ *impracticable*, on its packaging or in a document accompanying the device.

He shall ensure that he has in place a quality management system that includes procedures which ensure that the translation of information is accurate and up-to-date, and that the activities mentioned in points (a) and (b) of paragraph 2 are performed by means and under conditions that preserve the original condition of the device and that the packaging of the repackaged device is not defective, of poor quality or untidy. Part of the quality management system shall be procedures ensuring that the distributor or importer is informed of any corrective action taken by the manufacturer in relation to the device in question in order to respond to safety issues or to bring it in conformity with this Regulation.

4. Prior to making the relabelled or repackaged device available, the distributor or importer referred to in paragraph 3 shall inform the manufacturer and the competent authority of the Member State where he plans to make the device available and, upon request, shall provide them with a sample or a mock-up of the relabelled or repackaged device, including any translated label and instructions for use. He shall submit to the competent authority a certificate, issued by a notified body referred to in Article 27, designated for the type of devices that are subject to activities mentioned in points (a) and (b) of paragraph 2, attesting that the quality management system complies with the requirements laid down in paragraph 3.

## *Article 15*

### *EU declaration of conformity*

1. The EU declaration of conformity shall state that fulfilment of the requirements specified in this Regulation has been demonstrated. It shall be continuously updated. The minimum content of the EU declaration of conformity is set out in Annex III. It shall be translated into ~~the~~*an* official Union language or languages required by the Member State(s) in which the device is made available.
2. Where, concerning aspects not covered by this Regulation, devices are subject to other Union legislation which also requires a declaration of conformity by the manufacturer that fulfilment of the requirements of that legislation has been demonstrated, a single EU declaration of conformity shall be drawn up in respect of all Union acts applicable to the device containing all information required for identification of the Union legislation to which the declaration relates.
3. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for compliance with the requirements of this Regulation and all other Union legislation applicable to the device.
4. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing the minimum content of the EU declaration of conformity set out in Annex III in the light of technical progress.

## *Article 16*

### *CE marking of conformity*

1. Devices, other than devices for performance evaluation, considered to be in conformity with the requirements of this Regulation shall bear the CE marking of conformity, as presented in Annex IV.

2. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.
3. The CE marking shall be affixed visibly, legibly and indelibly to the device or its sterile pack. Where that is not possible or not warranted on account of the nature of the device, it shall be affixed to the packaging. The CE marking shall also appear in the instructions for use and on the sales packaging where those are provided.
4. The CE marking shall be affixed before the device is placed on the market. It may be followed by a pictogram or any other mark indicating a special risk or use.
5. Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 40. The identification number shall also be indicated in any promotional material which mentions that a device fulfils the legal requirements for CE marking.
6. Where devices are subject to other Union legislation concerning other aspects which also provide for the affixing of the CE marking, the CE marking shall indicate that the devices also fulfil the provisions of the other legislation.

#### *Article 17*

##### *Devices for special purposes*

1. Member States shall not create any obstacle to devices for performance evaluation which are supplied for that purpose to laboratories or other institutions, if they meet the conditions laid down in Articles 48 to 58.
2. Those devices shall not bear the CE marking, with the exception of the devices referred to in Article 52.



3. At trade fairs, exhibitions, demonstrations or similar events, Member States shall not create any obstacle to the showing of devices which do not comply with this Regulation, provided that ~~such devices are not used on specimens taken from participants~~ a visible sign clearly indicates that such devices are intended for presentation or demonstration purposes only and cannot be made available until they have been made to comply with this Regulation.

### *Article 18*

#### *Systems and procedure packs*

1. ~~Any natural or legal person shall draw up a statement referred to in paragraph 2 if he puts devices bearing the CE marking together with the following other devices or products, in accordance with the intended purpose of the devices or other products and within the limits of use specified by their manufacturers, in order to place them on the market as a system or procedure pack:~~
- ~~(a) other devices bearing the CE marking;~~
  - ~~(b) medical devices bearing the CE marking in conformity with Regulation (EU) [Ref. of future Regulation on medical devices];~~
  - ~~(c) other products which are in conformity with the legislation applicable to those products.~~
2. ~~In the statement, the person referred to in paragraph 1 shall declare the following:~~
- ~~(a) that he verified the mutual compatibility of the devices and, if applicable other products, in accordance with the manufacturers' instructions and has carried out his operations in accordance with those instructions;~~
  - ~~(b) that he packaged the system or procedure pack and supplied relevant information to users incorporating the information to be supplied by the manufacturers of the devices or other products which have been put together;~~
  - ~~(c) that the activity of putting devices and, if applicable, other products together as a system or procedure pack was subject to appropriate methods of internal monitoring, verification and validation.~~

3. Any natural or legal person who sterilises systems or procedure packs referred to in paragraph 1 for the purpose of placing them on the market shall, at his choice, follow one of the procedures referred to in Annex VIII or in of Annex X. The application of those Annexes and the involvement of the notified body shall be limited to the aspects of the procedure relating to ensuring sterility until the sterile package is opened or damaged. The person shall draw up a statement declaring that the sterilisation has been carried out in accordance with the manufacturer's instructions.
4. Where the system or procedure pack incorporate devices which do not bear the CE marking or where the chosen combination of devices is not compatible in view of their original intended purpose, the system or procedure pack shall be treated as a device in its own right and shall be subjected to the relevant conformity assessment procedure pursuant to Article 40.
5. The systems or procedure packs referred to in paragraph 1 shall not themselves bear an additional CE marking but they shall bear the name, registered trade name or registered trade mark of the person referred to in paragraph 1 as well as the address at which he can be contacted and his location can be established. Systems or procedure packs shall be accompanied by the information referred to in Section 17 of Annex I. The statement referred to in paragraph 2 of this Article shall be kept at the disposal of the competent authorities, after the system or procedure pack has been put together, for the period that is applicable to the devices put together in accordance with Article 8(4). Where these periods differ, the longest period shall apply.

## *Article 19*

### *Parts and components*

Any natural or legal person who makes available on the market an article intended specifically to replace an identical or similar integral part or component of a device that is defective or worn in order to maintain or re-establish the function of the device ~~without significantly changing its performance or safety characteristics~~, shall ensure that the article does not adversely affect the safety and performance of the device. ~~Substantiating~~ **Supporting** evidence shall be kept available to the competent authorities of the Member States.

An article that is intended specifically to replace a part or component of a device and that significantly changes the performance or safety characteristics of the device shall be considered a device.

## *Article 20*

### *Free movement*

***Except where otherwise provided in this regulation,*** Member States shall not refuse, prohibit or restrict the making available or putting into service within their territory of devices which comply with the requirements of this Regulation.

## Chapter III

# Identification and traceability of devices, registration of devices and of economic operators, summary of safety and performance, European databank on medical devices

### *Article 21*

#### *Identification within the supply chain*

1. ***Distributors and importers shall co-operate with the manufacturer or authorized representative to achieve an appropriate level of traceability of devices.***
  
2. ***Economic*** ~~For devices, other than devices for performance evaluation, economic operators shall be able to identify the following ***to the competent authority***, for the period referred to in Article 8(4):~~
  - (a) any economic operator to whom they have supplied a device;
  - (b) any economic operator who has supplied them with a device;
  - (c) any health institution ~~or healthcare professional~~ to whom they have supplied a device.~~Upon request, they shall inform the competent authorities thereof.~~

### *Article 21a*

#### *Medical devices nomenclature*

***To facilitate the functioning of the European Databank on medical devices (Eudamed) established pursuant to Article 27 of Regulation (EU) [Ref. of future Regulation on medical devices] and the UDI database established pursuant to Article 24a of Regulation (EU) [Ref. of future Regulation on medical devices] the Commission shall ensure that a medical devices nomenclature shall be available free of charge to manufacturers, natural or legal persons required to use nomenclature for the purpose of this regulation. The Commission shall also endeavour to ensure that that nomenclature is available to other stakeholders free of charge, where reasonably practicable.***

Article 22

*Unique device identification system*

1. ~~For devices, other than devices for performance evaluation, a system for Unique Device Identification shall be put in place in the Union.~~ The ***Unique Device Identification (UDI)*** system shall allow the identification and ***facilitate the*** traceability of devices, ***other than a device for performance evaluation***, and shall consist of the following:
  - (a) production of a UDI that comprises the following:
    - (i) a device identifier (***DI***) specific to a manufacturer and a device model, providing access to the information laid down in Part B of Annex V;
    - (ii) a production identifier (***PI***) that identifies ***the produced device's unit and if applicable the packaged devices as specified in Annex V Part C*** data related to ~~the unit of device production~~;
  - (b) ~~placement~~ ***application*** of the UDI on the label of the device ***or on its package***;
  - (c) ~~storage of the UDI by the economic operators and the health institutions through electronic means~~;
  - (d) establishment of an electronic system on UDI (***UDI database***) ***according to Article 24a of Regulation (EU) [Ref. of future Regulation on medical devices]***.

2. The Commission shall designate one or several entities that operate a system for assignment of UDIs pursuant to this Regulation and that satisfy all of the following criteria:
- (a) the entity is an organisation with legal personality;
  - (b) its system for the assignment of UDIs is adequate to identify a device through its distribution and use in accordance with the requirements of this Regulation;
  - (c) its system for the assignment of UDIs conforms to ~~the~~ **a** relevant international standards;
  - (d) the entity gives access to its system for the assignment of UDIs to all interested users according to a set of predetermined and transparent terms and conditions;
  - (e) the entity undertakes the following:
    - (i) to operate its system for the assignment of UDIs ~~for the period to be determined in the designation which shall at least be three~~ **ten** years after its designation;
    - (ii) to make available to the Commission and to the Member States, upon request, information concerning its system for the assignment of UDIs ~~and concerning manufacturers that place an UDI on the label of their device in accordance with the entity's system;~~
    - (iii) to remain in compliance with the criteria for designation and the terms of designation ~~during the period for which it is designated.~~

*In exercising its powers under this paragraph the Commission shall endeavour to promote interoperability between different UDI assigning entity systems with a view to minimising financial and administrative burdens for economic operators and health institutions.*

3. Before placing a device on the market, the manufacturer shall assign to the device **and if applicable – to all higher levels of packaging** a UDI **created in compliance with the rules of** ~~provided by~~ an entity designated by the Commission in accordance with paragraph 2, ~~if that device belongs to the devices, categories or groups of devices determined by a measure referred to in point (a) of paragraph 7.~~

4. The UDI *carrier* shall be placed on the label of the device **and on all higher levels of packaging. Higher levels of packaging do not include shipping containers.** ~~in accordance with the conditions laid down by a measure referred to in point (c) of paragraph 7. It shall be used for reporting serious incidents and field safety corrective actions in accordance with Article 59. The device identifier shall appear on the EU declaration of conformity referred to in Article 15 and in the technical documentation referred to in Annex II.~~
- 4a. The UDI shall be used for reporting serious incidents and field safety corrective actions in accordance with Article 59**
- 4b. The Basic UDI device identifier (Basic UDI-DI as defined in Annex V Part C) of the device shall appear on the EU declaration of conformity referred to in Article 15.**
- 4c. The manufacturer has to keep up-to-date a list of all applied UDI as part of the technical documentation referred to in Annex II.**
5. Economic operators and health institutions shall store and keep, **preferably** by electronic means, the **UDI device identifier and the production identifier** of the devices which they have supplied or they have been supplied with, if they belong to the devices, categories or groups of devices determined by a measure referred to in point (a) of paragraph 7.
- 5a. Member States shall encourage, and may require, health care professionals and health institutions to store and keep, preferably by electronic means, the UDI of the devices which they have been supplied with. With a view to ensuring a uniform approach to the manner in which the UDI of devices, categories or groups of devices which health institutions have been supplied with is to be stored, the Commission may adopt implementing acts pursuant to point (aa) of paragraph 7.**

6. ~~The Commission, in cooperation with the Member States, shall set up and manage an electronic system on UDI to collate and process the information mentioned in Part B of Annex V. This information shall be accessible to the public.~~
7. The Commission ~~shall be empowered to~~ *may, by means of* ~~adopt delegated~~ **implementing acts** *specify the modalities and the procedural aspects with a view to ensuring harmonised application of the Unique Device Identification System for any of the following aspects* ~~in accordance with Article 85:~~
- (a) ~~determining~~ **the determination of** the devices, categories or groups of devices, whose identification shall be based on the ~~to which the obligation laid down in paragraph 5 shall apply~~ UDI system, as set out in paragraphs 1 to 6, and the timelines for implementing this. Following a risk-based approach, implementation of the UDI system shall be gradual, starting with devices falling in the highest risk class;
  - (aa) **the determination of the devices, categories or groups of devices to which paragraph 5a shall apply;**
  - (b) ~~specifying~~ **the specification of** the data to be included in the **UDI** production identifier (**UDI-PI**) **of specific devices or device groups** which, following a risk-based approach, may vary depending on the risk class of the device;
  - (c) ~~defining the obligations of economic operators, of health institutions and of professional users, in particular regarding allocation of the numeric or alphanumeric characters, placement of the UDI on the label, storage of information in the electronic system on UDI, and use of the UDI in documentation and reporting related to the device provided for in this Regulation;~~

***Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).***



- 7a. The Commission shall be empowered to adopt delegated acts in accordance with Article 85:**
- (a)** amending or supplementing the list of information set out in Part B of Annex V in the light of technical progress; *and*
  - (b)** *amending or supplementing of Annex V in the light of international development in the field of unique device identification.*
8. When adopting the measures referred to in paragraph 7, the Commission shall take into account the following:
- (a) the protection of personal data;
  - (b) the legitimate interest in protecting commercially sensitive information;
  - (c) the risk-based approach;
  - (d) the cost-effectiveness of the measures;
  - (e) the convergence of UDI systems developed at international level;
  - (f)** *the need to avoid duplications in the UDI system-;*
  - (g)** *the needs of the health care systems of the Member States.*

#### **Article 22a**

##### ***Electronic system on UDI (UDI database)***

- 1. The Commission, after consulting the MDCG shall set up and manage an electronic system on UDI (UDI database) in accordance with the conditions and modalities established by Article 24a of Regulation (EU) [Ref. of future Regulation on medical devices].**
- 2. Before a device, other than a device for performance evaluation, is placed on the market the manufacturer or his authorised representative must ensure that the information referred to in Part B of Annex V of the device in question are correctly submitted and transferred to the UDI database.**

*Article 22b*

*Process for registration of devices*

- 1. Before the device is placed ~~plac~~ing on the market, the manufacturer of a device, other than custom made or investigational devices, shall, ~~assign~~ in compliance with the rules of the designated issuing entities, assign to the device a Basic UDI-DI as defined in Annex V Part C.*
  
- 2. Where a manufacturer of ~~a~~ devices, other than devices for performance evaluation, applies a conformity assessment procedure according to Article 40(3) first sentence, (4) or (5) the manufacturer shall submit to the UDI database the Basic UDI-DI and the linked information referred to in Part B of Annex V before placing the device on the market.*

3. *Where a manufacturer of devices, other than devices for performance evaluation, applies a conformity assessment procedure according to Article 40 (2) or (3) second sentence (EC technical documentation assessment, EC type-examination) the manufacturer shall assign the Basic UDI-DI (Annex V Part C) to the device before applying for a conformity assessment procedure by a notified body.*

*The Notified Body shall reference the Basic UDI-DI on the certificate issued (Annex XII I 4.a). After the issuing of the relevant certificate and before placing the device on the market the manufacturer or his authorised representative shall submit to the UDI database the Basic UDI-DI and the linked information referred to in Part B of Annex V.*

#### *Article 23*

##### *Electronic system on registration of ~~devices and~~ economic operators*

1. The Commission, ~~in collaboration with the Member States~~ **after consulting the MDCG**, shall set up and manage an electronic system to **create the single registration number referred to in Article 23a and to** collate and process information that is necessary and proportionate to ~~describe and identify the device and to identify the manufacturer and, where applicable, the authorised representative and the importer~~ The details regarding the information to be submitted by the economic operators are laid down in Part A of Annex V.
  - 1b. *Member States may maintain or introduce national provisions on registration of distributors and importers of a device which have been made available in their territory.*
2. ~~Before a device, other than a device for performance evaluation, is placed on the market the manufacturer or his authorised representative shall submit to the electronic system the information referred to in paragraph 1.~~

3. Within ~~one~~ **two** weeks after placing a device, other than a device for performance evaluation, on the market, importers shall ~~submit~~ **verify that the manufacturer or authorised representative has uploaded** to the electronic system the information referred to in paragraph 1 **and shall add their details to the relevant entry/entries.**

*Where applicable, importers shall also verify that the registration includes the details of the authorised representative and, if these details are not included, shall inform the relevant authorised representative.*

#### *Article 23a*

##### *Process for registration of manufacturers and Authorised Representatives, Single registration number*

1. *The manufacturer or his authorised representative, who has not been registered before according to this article shall submit to the electronic system the information referred to in Annex V Part A before placing a device, other than a device for performance evaluation, on the market. In cases where the conformity assessment procedure requires the involvement of a notified body the information referred to in Annex V part A shall be submitted to the electronic system before applying to a notified body.*
2. *After having verified the data entered by the manufacturer or his authorised representative the competent authority shall procure from the electronic system referred to Article 23 a single registration number and issue it to the manufacturer or his authorised representative.*

3. ***The manufacturer shall use the single registration number when applying to a notified body for certification according to Article 41 and for entering the electronic system on UDI (in order to fulfil their obligations according to Article 22a(2) and Article 22b(2) and (3)).***
4. Within one week of any change occurring in relation to the information referred to in paragraph 1, the relevant economic operator shall update the data in the electronic system.
5. Not later than ~~two~~ ***one*** years after submission of the information in accordance with ***paragraph 1*** ~~paragraphs 2 and 3~~, and then every second year ***thereafter***, the relevant economic operator shall confirm the accuracy of the data. ***Without prejudice to the economic operator's responsibility for the data, the competent authority shall verify the confirmed data referred to in points 1-4a of Part A of Annex V.*** In the event of failure to confirm within six months of the due date, any Member State may take ***appropriate corrective*** measures ~~to suspend or otherwise restrict the making available of the device in question~~ within its territory until the obligation referred to in this paragraph is complied with.
6. The data contained in the electronic system shall be accessible to the public.
7. ***The competent authority may use the data to administer a charge or fee to the manufacturer or the authorised representative pursuant to Article 82.***

## Article 24

### Summary of safety and performance

1. In the case of devices classified as class C and D, other than devices for performance evaluation, the manufacturer shall draw up a summary of safety and performance. It shall be written in a way that is clear to the intended user **and, if relevant, to the patient and shall be available to the public via Eudamed**. The draft of this summary shall be part of the documentation to be submitted to the notified body involved in the conformity assessment in accordance with Article 40 and shall be validated by that body. **After validation the notified body shall upload this summary report to Eudamed. The manufacturer shall mention on the label or instructions for use where the summary report is available.**
  - 1a. **The summary of safety and performance shall include at least the following aspects:**
    - (a) **the identification of the device and the manufacturer, including the basic UDI-DI and the single registration number;**
    - (b) **the intended purpose of the device, including indications, contra-indications and target populations;**
    - (c) **a description of the device, including a reference to previous generation(s) or variants if such exist, and the description of the differences, as well as a description of the accessories, other in vitro diagnostic medical devices and other products that are not in vitro diagnostic medical devices, which are intended to be used in combination with the in vitro diagnostic medical device;**
    - (d) **reference to harmonized standards and common (technical) specifications;**
    - (e) **the summary of the performance evaluation report as referred to in annex XII, and relevant information on the PMPF;**
    - (f) **the metrological traceability of assigned values;**
    - (g) **suggested profile and training for users;**
    - (h) **information on any residual risks and any (indirect) undesirable effects, warnings and precautions.**

2. The Commission may, by means of implementing acts, set out the form and the presentation of the data elements to be included in the summary of safety and performance. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 84(2).

*Article 25*

*European databank*

The Commission, **after consulting the MDCG**, shall develop and manage the European databank on medical devices (Eudamed) in accordance with the conditions and modalities established by Article 27 of Regulation (EU) [Ref. of future Regulation on medical devices].

Eudamed shall include the following ~~as integral parts~~:

- (a) the electronic system on UDI referred to in Article 22;
- (b) the electronic system on registration of ~~devices and~~ economic operators referred to in Article 23;
- (ba) the electronic system on notified bodies referred to in Article 31(9);**
- (c) the electronic system on information **on application for conformity assessments and** on certificates referred to in **Article 41(1) and** Article 43(4) **and on summaries of safety and clinical performance referred to in Article 24;**
- (d) the electronic system on interventional ~~clinical~~ performance studies and clinical performance studies involving risks for the subjects set up in Article 51;
- (e) the electronic system on vigilance **and post-market surveillance** referred to in Article ~~66~~ **64a**;
- (f) the electronic system on market surveillance referred to in Article ~~66~~ **73b**.

## Chapter IV

### Notified Bodies

#### Article 26

##### *National authorities responsible for notified bodies for in vitro diagnostic medical devices*

1. A Member State that intends to designate a conformity assessment body as a notified body, or has designated a notified body, to carry out ~~third-party~~ conformity assessment ~~tasks~~ **activities** under this Regulation shall ~~designate~~ **nominate** an authority, **which may consist of separate constituent entities under national law**, that shall be responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, including subcontractors ~~or~~ **and** subsidiaries of those bodies, hereinafter referred to as the ‘national authority responsible for notified bodies’.
2. The national authority responsible for notified bodies shall be established, organised and operated so as to safeguard the objectivity and impartiality of its activities and to avoid any conflicts of interests with conformity assessment bodies.
3. **The national authority responsible for notified bodies** ~~It~~ shall be organised so that each decision relating to **designation or** notification ~~of a conformity assessment body~~ is taken by personnel different from those who carried out the assessment ~~of the conformity assessment body~~.
4. **The national authority responsible for notified bodies** ~~It~~ shall not perform any activities that ~~conformity assessment~~ **notified** bodies perform ~~nor provide consultancy services on a commercial or competitive basis~~.



5. The national authority responsible for notified bodies shall safeguard the confidentiality of the information it obtains. However, it shall exchange information on a notified body with other Member States ~~and~~, the Commission **and with other regulatory authorities**.
6. The national authority responsible for notified bodies shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

~~Where Without prejudice to Article 31(3), where a~~ **the** national authority is responsible for the designation of notified bodies in the field of products other than *in vitro* diagnostic medical devices, **is a different authority than the national** competent authority for *in vitro* diagnostic medical devices, **it shall ensure that the authority responsible for in vitro diagnostic medical devices is consulted** shall be consulted on all **relevant** aspects specifically related to such devices.

7. Member States shall **make publicly available general information** ~~provide the Commission and the other Member States with information~~ on their procedures for **provisions on** the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, and **on** ~~of any~~ changes **which have a significant impact on these tasks** ~~thereto~~.
8. The national authority responsible for notified bodies shall **participate in oversight activities laid down in Article 36**. ~~be peer-reviewed every second year. The peer-review shall include an on-site visit to a conformity assessment body or a notified body under the responsibility of the reviewed authority. In the case referred to in the second subparagraph of paragraph 6, the competent authority for medical devices shall participate in the peer review.~~

~~The Member States shall draw up the annual plan for the peer review, ensuring an appropriate rotation in respect of reviewing and reviewed authorities, and submit it to the Commission. The Commission may participate in the review. The outcome of the peer review shall be communicated to all Member States and to the Commission and a summary of the outcome shall be made publicly available.~~

## Article 27

### *Requirements relating to notified bodies*

1. Notified bodies shall satisfy the organisational and general requirements and the quality management, resource and process requirements that are necessary ***so they are qualified to*** fulfil their tasks for which they are designated in accordance with this Regulation. ~~Minimum~~ ***The requirements*** to be met by notified bodies are set out in Annex VI.
  - 1a. ***Notified bodies shall make available and submit upon request, all relevant documentation, including the manufacturer's documentation to the national authority responsible for notified bodies to allow it to conduct its assessment, designation, notification, monitoring and surveillance activities and to facilitate the assessment outlined within this Chapter.***
2. ***In order to ensure the uniform application of the requirements set out in Annex VI,*** The Commission shall be empowered to ~~may~~ adopt delegated ***implementing*** acts in accordance with Article 849(3) ~~amending or supplementing the minimum requirements in Annex VI, in the light of technical progress and considering the minimum requirements needed for the assessment of specific devices, or categories or groups of devices.~~

## Article 28

### *Subsidiaries and subcontracting*

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary for specific tasks connected with conformity assessment, it shall verify that the subcontractor or the subsidiary meets the ~~relevant~~ ***applicable*** requirements set out in Annex VI and shall inform the national authority responsible for notified bodies accordingly.

2. Notified bodies shall take full responsibility for the tasks performed on their behalf by subcontractors or subsidiaries.
3. Conformity assessment activities may be subcontracted or carried out by a subsidiary only ~~with the agreement of the~~ **provided that the** legal or natural person that applied for conformity assessment **has been informed of this**.
4. Notified bodies shall keep at the disposal of the national authority responsible for notified bodies the relevant documents concerning the verification of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation.

#### *Article 29*

##### *Application by a conformity assessment body for ~~notification~~ designation*

1. A conformity assessment body shall submit an application for ~~notification~~ **designation** to the national authority responsible for notified bodies of the Member State in which it is established.
2. The application shall specify the conformity assessment activities **as defined in this Regulation** ~~the conformity assessment procedures~~ and the **types of** devices for which the body **applies to be designated and for which involvement of a notified body is required** ~~claims to be competent~~, supported by documentation proving compliance with all the requirements set out in Annex VI.

In respect of the organisational and general requirements and the quality management requirements set out in Sections 1 and 2 of Annex VI, ~~the relevant documentation may be submitted in form of a valid certificate and the corresponding evaluation report delivered by a national accreditation body in accordance with Regulation (EC) No 765/2008. The conformity assessment body shall be presumed to be in conformity with the requirements covered by the certificate delivered by such accreditation body~~ **may be submitted in support of these requirements and shall be taken into consideration during the assessment described in Article 30. However, the applicant shall make available the full documentation to demonstrate conformity with these requirements upon request.**

3. After being designated, the notified body shall update the documentation referred to in paragraph 2 whenever relevant changes occur in order to enable the national authority responsible for notified bodies to monitor and verify continuous compliance with all the requirements set out in Annex VI.

#### *Article 30*

##### *Assessment of the application*

1. The national authority responsible for notified bodies shall **within 30 days** check that the application referred to in Article 29 is complete and **shall request the applicant to provide any missing information. Once the application is complete the national authority shall send it to the Commission along with a proposed timeframe for preliminary review and an indicative date for an on-site assessment.**

***The national authority shall review the application and supporting documentation in accordance with its own procedures and shall draw up a preliminary assessment report.***

2. ~~It~~ ***The national authority responsible for notified bodies*** shall submit the preliminary assessment report to the Commission which shall immediately transmit it to the Medical Device Coordination Group (~~'MDCG'~~) referred to in established by Article 76 (***'MDCG'***). ***The national authority responsible for notified bodies shall also indicate based on their assessment whether the on-site assessment date proposed in paragraph 1 remains valid.*** Upon request by the Commission, the report shall be submitted by the authority in up to three official Union languages.

***Documents to support the application described in Article 29 shall be made available upon request.***

3. Within 14 days of the submission referred to in paragraph 2, the Commission ***in conjunction with the MDCG*** shall ~~designate~~ ***assign*** a joint assessment team made up of at least ~~two~~ ***three*** experts, ***unless the specific circumstances require another number of experts***, chosen from ~~a~~ ***the*** list of experts who are qualified in the assessment of conformity assessment bodies ***referred to in Article 30a*** ~~The list shall be drawn up by the Commission in cooperation with the MDCG. At least~~ ***One*** of these experts shall be a representative of the Commission who shall ~~lead~~ ***coordinate*** the ***activities of the*** joint assessment team.
- 3a. ***The joint assessment team shall be comprised of competent experts which reflect the conformity assessment activities and the types of devices which are subject to the application or, in particular when this procedure is initiated in accordance with Article 35 to ensure that the specific concern can be appropriately assessed.***

4. Within 90 days after designation **assignment** of the joint assessment team, ~~the national authority responsible for notified bodies and the joint assessment team~~ shall review the documentation submitted with the application in accordance with Article 29. ***The joint assessment team may feedback to or require clarification from the national authority responsible for notified bodies on the application and on the planned on-site assessment.***

***The national authority responsible for notified bodies together with the joint assessment team shall ~~and plan~~ and conduct an on-site assessment of the applicant conformity assessment body and, where relevant, of any subsidiary or sub-contractor, located inside or outside the Union, to be involved in the conformity assessment process.***

~~Such on-site assessment shall not cover requirements for which the applicant conformity assessment body has received a certificate delivered by the national accreditation body as referred to in Article 29(2), unless the Commission representative mentioned in Article 30(3) requests the on-site assessment.~~

***The on-site assessment of the applicant body shall be led by the national authority responsible for notified bodies.***

- 4a. Findings regarding non-compliance of a body with the requirements set out in Annex VI shall be raised during the assessment process and discussed between the national authority responsible for notified bodies and the joint assessment team with a view to finding common agreement ***and resolution of any diverging opinions*** with respect to the assessment of the application.

***A list of non-compliances resulting from the assessment shall be presented by the national authority responsible for notified bodies to the applicant body at the end of the on-site assessment including a summary of the assessment delivered by the joint assessment team.***

*The national authority shall request a corrective and preventive action plan from the applicant body to be submitted within a specified timeframe to address the non-compliances.*

~~Divergent opinions shall be identified in the assessment report of the national authority responsible.~~

*4aa. The joint assessment team shall within 30 days of completion of the on-site assessment document any remaining diverging opinions with respect to the assessment and send these to the national authority responsible for notified bodies.*

*4b. The national authority responsible for notified bodies shall following receipt of a corrective and preventive action plan from the applicant body assess whether non-compliances identified during the assessment have been appropriately addressed. This plan shall include an indication of the root cause of the finding and a timeframe for implementation of the actions therein.*

*The national authority shall having confirmed the corrective and preventive action plan forward this plan and its opinion on this plan to the joint assessment team. The joint assessment team may request further clarification and modifications from the national authority responsible for notified bodies.*

*The national authority responsible for notified bodies shall draw up its final assessment report which shall include:*

- the result of the assessment,*
- confirmation that the corrective and preventive actions have been appropriately addressed and, where required, implemented,*
- any remaining diverging opinion with the joint assessment team, and, where applicable,*
- the recommended scope of designation.*

5. The national authority responsible for notified bodies shall submit its **final** assessment report and, **if applicable, the** its draft notification **designation** to the Commission, ~~which shall immediately transmit those documents to the MDCG and to the members of the joint assessment team. Upon request by the Commission, those documents shall be submitted by the authority in up to three official Union languages.~~
6. The joint assessment team shall provide its opinion **in a final report** regarding the assessment report **prepared by the national authority responsible for notified bodies** and, **if applicable,** the draft notification **designation** within 21 days of receipt of those documents ~~and to the Commission,~~ **which** shall immediately submit this opinion to the MDCG. Within ~~21~~ **42** days after receipt of the opinion of the joint assessment team, the MDCG shall issue a recommendation with regard to the draft notification **designation** which the ~~relevant~~ national authority shall duly take into consideration for its decision on the designation of the notified body.
7. The Commission may, by means of implementing acts, adopt measures setting out the modalities **specifying procedures and reports** for the application for notification **designation** referred to in Article 29 and the assessment of the application set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

#### *Article 30a*

##### *Nomination of experts for joint assessment of applications for notification*

1. ***The Member States and the Commission shall nominate experts qualified in the assessment of conformity assessment bodies in the field of in vitro diagnostic medical devices to participate in the activities outlined in Article 30 and Article 36.***
2. ***The Commission shall maintain a list of the experts nominated pursuant to paragraph 1, together with information on their specific competence and expertise. This list shall be made available to Member States competent authorities through the electronic system referred to in Article 25.***



## *Article 30b*

### *Language requirements*

*All documents required pursuant to Articles 29 and 30 shall be drawn up in a language or languages which shall be determined by the Member State concerned.*

*Member States, in applying the first sub-paragraph, shall consider accepting and using a commonly understood language in the medical field, for all or part of the documents concerned.*

*The Commission shall provide necessary translations of the documentation pursuant to Article 29 and 30, or parts of it thereof into an official Union language such that the documents can be readily understood by the joint assessment team designated in accordance with Article 30(3).*

## *Article 31*

### *Designation and notification procedure*

- 0. Member States may only designate conformity assessment bodies which satisfy the requirements set out in Annex VI and for which the assessment pursuant to Article 30 was completed.*
- 1. Member States shall notify the Commission and the other Member States of the conformity assessment bodies they have designated, using the electronic notification tool developed and managed by the Commission.*
- 2. Member States may notify only conformity assessment bodies which satisfy the requirements set out in Annex VI.*
- 3. Where a national authority responsible for notified bodies is responsible for designation of notified bodies in the field of products other than diagnostic medical devices, the competent authority for *in vitro* diagnostic medical devices shall provide prior to the notification, a positive opinion on the notification and its scope.*

4. The notification shall clearly specify the scope of the designation indicating the conformity assessment activities *as defined in this Regulation*, ~~the conformity assessment procedures~~ and the type of devices which the notified body is authorised to assess *and, without prejudice to Article 33, any conditions associated with the designation*.
- 4a. The Commission *shall within six months of the entry into force of this Regulation* ~~may~~, by means of implementing acts, ~~set~~ *draw* up a list of codes and ~~the~~ corresponding types of devices to ~~define~~ *describe* the scope of the designation of notified bodies which the Member States shall indicate in their notification. Those implementing acts shall be adopted in accordance with the advisory *examination* procedure referred to in Article 84(2 3). *The Commission, after consulting the MDCG, may update this list inter alia based on information arising from the coordination activities described in Article 36.*
5. The notification shall be accompanied by the final assessment report of the national authority responsible for notified bodies, ~~the opinion~~ *final report* of the joint assessment team and the recommendation of the MDCG. Where the notifying Member State does not follow the recommendation of the MDCG, it shall provide a duly substantiated justification.
6. The notifying Member State shall, *without prejudice to Article 33*, provide the Commission and the other Member States *of any conditions associated with the designation and provide* documentary evidence regarding the arrangements in place to ensure that the notified body will be monitored regularly and will continue to satisfy the requirements set out in Annex VI. ~~It shall furthermore submit evidence of the availability of competent personnel for monitoring the notified body in accordance with Article 26(6).~~
7. Within 28 days of a notification, a Member State or the Commission may raise written objections, setting out its arguments, with regard either to the notified body or to its monitoring by the national authority responsible for notified bodies.

8. When a Member State or the Commission raises objections in accordance with paragraph 7, ~~the effect of the notification shall be suspended. In this case,~~ the Commission shall bring the matter before the MDCG within ~~150~~ days after expiry of the period referred to in paragraph 7. After consulting the parties involved, the MDCG shall give its opinion at the latest within ~~40~~ ~~28~~ days after the matter has been brought before it. ~~If the notifying Member State does not agree with the opinion of the MDCG, it may request the Commission to give its opinion.~~
- 8a. Where the MDCG, after having been consulted in accordance with paragraph 8, confirms the existing objection or raises another objection, the notifying Member State shall provide a written response to the MDCG's opinion within 40 days of its receipt. The response shall address the objections raised in the opinion, and set out the reasons for the notifying Member State's decision to designate or not designate the conformity assessment body.*
9. Where no objection is raised in accordance with paragraph 7 or where the MDCG ~~or the Commission~~, after having been consulted in accordance with paragraph 8, is of the opinion that the notification may be accepted ~~fully or partially,~~ *or where the notifying Member State having responded in accordance with paragraph 8a, decides to designate the conformity assessment body* the Commission shall publish the notification accordingly *within 14 days of receipt.*
- When publishing the notification in the database of notified bodies developed and managed by the Commission the Commission shall add the information relating to the notification of the notified body to the electronic system referred to in Article 25 along with the documents mentioned in paragraph 5 and the opinion and response referred to in paragraphs 8 and 8a of this Article.*
10. The notification shall become valid the day after its publication in the database of notified bodies developed and managed by the Commission. The published notification shall determine the scope of lawful activity of the notified body.
- 11. The conformity assessment body concerned may perform the activities of a notified body only after the notification has become valid in accordance with paragraph 10.*

## Article 32

### *Identification number and list of notified bodies*

1. The Commission shall assign an identification number to each notified body for which the notification is accepted **becomes valid** in accordance with Article 31(10). It shall assign a single identification number even when the body is notified under several Union acts.
2. The Commission shall make ~~accessible to the public~~ the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the **conformity assessment activities as defined in this Regulation and the types of devices** for which they have been notified, **accessible to the public in the database of notified bodies developed and managed by the Commission. It shall also make this list available on the electronic system referred to in Article 25.** The Commission shall ensure that the list is kept up to date.

## Article 33

### *Monitoring and assessment of notified bodies*

0. **Notified bodies shall, without delay, inform the national authority responsible for notified bodies of relevant changes which may affect their compliance with the requirements set out in Annex VI or their ability to conduct the conformity assessment activities relating to the devices for which they have been designated.**
1. The national authority responsible for notified bodies shall ~~continuously~~ **conduct monitoring of** the notified bodies **based on its territory and of their subsidiaries and subcontractors** to ensure ongoing compliance with the requirements **and the fulfilment of its obligations** set out in **this Regulation Annex VI**. The notified bodies shall, on request **from the national authority responsible for notified bodies**, supply all relevant information and documents, required to enable the authority, **the Commission and other Member States** to verify compliance with those criteria.

Notified bodies shall, without delay, inform the national authority responsible for notified bodies of any changes, in particular regarding their personnel, facilities, subsidiaries or subcontractors, which may affect compliance with the requirements set out in Annex VI or their ability to conduct the conformity assessment procedures relating to the devices for which they have been designated.

2. ***The national authority responsible for notified bodies shall receive a copy of all requests submitted by the Commission or by another Member State authority to notified bodies on its territory relating to conformity assessments such notified bodies have carried out.*** Notified bodies shall respond without delay to ***such*** requests relating to conformity assessments they have carried out, submitted by their or another Member State's authority or by the Commission. The national authority responsible for notified bodies of the Member State in which the body is established shall ~~enforce~~ ***ensure that*** requests submitted by authorities of any other Member State or by the Commission ***are resolved*** unless there is a legitimate reason for not doing so in which case both sides may consult the MDCG. ~~The notified body or their national authority responsible for notified bodies may request that any information transmitted to the authorities of another Member State or to the Commission shall be treated as confidential.~~
3. At least once a year, the national authority responsible for notified bodies shall assess whether each notified body ***and, when appropriate, the subsidiaries and subcontractors*** under its responsibility still satisfies the requirements ***and fulfil their obligations*** set out in Annex VI. This ~~assessment~~ ***review*** shall include an on-site visit to each notified body ***and, when necessary, to its subsidiaries and subcontractors.***

***The national authority shall conduct its monitoring, and assessment activities according to an annual assessment plan to ensure that it can effectively monitor the continued compliance of the notified body with the requirements of this Regulation. This plan shall provide a reasoned schedule for the frequency of assessment of the notified body and associated subsidiaries and subcontractors. The authority shall submit its annual plan for monitoring or assessment for each notified body for which it is responsible to the MDCG and to the Commission.***

- 3a. The national authority's monitoring of notified bodies shall include witnessed audits of the notified body personnel, including when necessary the personnel from subsidiaries and subcontractors, when conducting quality system assessments at a manufacturer's facility.**
- 3b. The monitoring of notified bodies conducted by national authorities responsible for notified bodies shall consider data arising from market surveillance, vigilance and post-market surveillance systems to help guide its activities.**

***The authority shall provide for a systematic follow-up of complaints, and other information, including from other Member States, which may indicate non-fulfilment of the obligations by a notified body or its deviation from common or best practice***

***The national authority responsible for notified bodies may in addition to regular monitoring or on-site assessments conduct short-notice, unannounced or 'for-cause' reviews if needed to address a particular issue or to verify compliance.***

- 3c. The national authority responsible for notified bodies shall assess the notified body assessments of manufacturers' technical and clinical documentation as further outlined in Article 33a.**
- 3d. The national authority responsible for notified bodies shall document and record any findings regarding non-compliance of the notified body with the requirements set out in Annex VI and shall monitor the timely implementation of relevant corrective and preventative actions.**

4. Three years after notification of a notified body, and again every ~~third~~ **fourth** year thereafter, the **re**-assessment to determine whether the notified body still satisfies the requirements set out in Annex VI shall be conducted by the national authority responsible for notified bodies of the Member State in which the body is established and a joint assessment team designated in accordance with the procedure described in Article 30(3) **29** and **30 (4)**. ~~At the request of the Commission or of a Member State, the MDCG may initiate the assessment process described in this paragraph at any time when there is reasonable concern about the ongoing compliance of a notified body with the requirements set out in Annex VI~~

**4a. The Commission may, by means of implementing acts, modify the frequency of complete re-assessment referred to in the previous sub-paragraph. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).**

5. The Member States shall report to the Commission and to the **MDCG** ~~other Member States~~, at least once a year, on their monitoring activities **regarding their notified bodies and, where applicable, subsidiaries and subcontractors. This report shall provide details of the outcome of the monitoring and surveillance activities.** This report **shall be treated as confidential by the MDCG and the Commission however it** shall contain a summary which shall be made publicly available.

***The summary report shall be uploaded to the European databank referred to in Article 25.***

### *Article 33a*

#### *Review of notified body assessment of technical documentation and performance evaluation documentation*

- 1. The national authority responsible for notified bodies, as part of its ongoing monitoring of notified bodies shall assess an appropriate number of notified body assessments of manufacturers' technical documentation and performance evaluations to verify the conclusions drawn by the notified body based on the information presented by the manufacturer. These assessments shall be conducted both off-site and on-site assessments.*
- 2. The sample of files assessed in accordance with paragraph 1 shall be planned and representative of the types and risk of devices certified by the notified body and in particular high risk devices appropriately justified and documented in a sampling plan, which shall be available from the national authority responsible for notified bodies upon request of the MDCG.*
- 3. The national authority responsible for notified bodies shall assess whether the assessment by the notified body was conducted appropriately and verify the procedures used, associated documentation and conclusions drawn by the notified body. This shall include the manufacturer's technical and clinical documentation upon which the notified body has based its assessment. These assessments shall be conducted utilising common technical specifications provided for in Article 7 in the conduct of the assessment.*
- 4. The assessments shall also form part of the re-assessment of notified bodies in accordance with Article 33(4) and the joint assessment activities referred to in Article 35(2a). These assessment shall be conducted utilising appropriate expertise.*



5. *The MDCG may, based on the reports of these assessments by the national authority or joint assessment teams, and inputs from the market surveillance and post-market surveillance activities described in Chapter VII, recommend that the sampling, either by national authority or as part of a joint assessment activity, shall cover a greater or lesser proportion of the performance evaluations and technical documentation assessed by a notified body.*
6. *The Commission may, by means of implementing acts, adopt measures setting out the modalities, associated documents for and coordination of the technical and clinical assessments referred to in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).*

#### *Article 34*

##### *Changes to **designations and notifications***

1. The Commission and the other Member States shall be notified of any subsequent relevant changes to the ~~notification~~ **designation by the national authority responsible for notified bodies**. The procedures described in Article 30(2) to (6) and in Article 31 shall apply to changes where they entail **an** extension of the scope of the notification. In all other cases, the Commission shall immediately publish the amended notification in the electronic notification tool referred to in Article 31(10).
  - 1a. *Where a notified body decides to cease its conformity assessment activities it shall inform the national authority responsible for notified bodies and the manufacturers concerned as soon as possible and in case of a planned ceasing its activities. The certificates may remain valid for a temporary period of nine months after cessation of activities on condition that another notified body has confirmed in writing that it will assume responsibilities for these products. The new notified body shall complete a full assessment of the devices affected by the end of that time period before issuing new certificates for those devices.*

2. Where a national authority responsible for notified bodies has ascertained that a notified body no longer meets the requirements set out in Annex VI, or that it is failing to fulfil its obligations *or has not implemented the necessary corrective measures*, the authority shall suspend, restrict, or fully or partially withdraw the ~~notification~~ *designation*, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. A suspension shall not exceed a period of one year, renewable once for the same period. Where the notified body has ceased its activity, the national authority responsible for notified bodies shall withdraw the notification.

The national authority responsible for notified bodies shall immediately inform the Commission and the other Member States of any suspension, restriction or withdrawal of a notification.

3. In the event of restriction, suspension or withdrawal of a notification, the Member State shall take appropriate steps to ensure that the files of the notified body concerned are ~~either processed by another notified body or~~ kept available for the national authorities responsible for notified bodies and *national authorities responsible* for market surveillance at their request.
4. The national authority responsible for notified bodies shall:
- assess ~~whether the reasons which gave rise to the change to the notification have an~~ *the* impact on the certificates issued by the notified body *where there is a change to the notification*; and,
  - *submit a report on its findings to the Commission and the other Member States* within three months after having notified the changes to the notification, ~~shall submit a report on its findings to the Commission and the other Member States.~~

- *require the notified body to suspend or withdraw, within a reasonable period of time determined by the authority, any certificates which were unduly issued, ~~Where necessary to ensure the safety of devices on the market, that authority shall instruct the notified body to suspend or withdraw, within a reasonable period of time determined by the authority, any certificates which were unduly issued. If the notified body fails to do so within the determined period of time, or has ceased its activity, the national authority responsible for notified bodies itself shall suspend or withdraw the certificates unduly issued.~~*
- *enter into the electronic system mentioned in Article 43 paragraph 4 all certificates for which it has required suspension or withdrawn.*
- *inform the competent authority for in vitro diagnostic medical devices of the Member State where the manufacturer or his authorised representative has his registered place of business through this electronic system referred to in Article 25 of the certificates for which it has required suspension or withdrawal. The competent authority responsible for the manufacturer of the device or his authorised representative shall take the appropriate measures where necessary to avoid a potential risk to the health or safety of patients, users or others.*

5. ~~The~~ *With the exception of* certificates, ~~other than those unduly issued, which were issued by the notified body for which the notification~~ *and where a designation* has been suspended, or restricted or withdrawn *the certificates* shall remain valid in the following circumstances:

- (a) ~~in the case of suspension of a notification: on condition that,~~ *the national authority responsible for notified bodies has confirmed within one month of the suspension or restriction, that there is no safety issue for certificates affected by the suspension or restriction and the national authority responsible for notified bodies has outlined a timeline and actions anticipated to remedy the suspension or restriction.*

*or:*

(b) *The authority responsible for notified bodies has confirmed, that no certificates relevant to the suspension will be issued, amended or re-issued during the course of the suspension/restriction and indicates whether the notified body has the capability of continuing to monitor and remain responsible for existing certificates issued for the period of the suspension or restriction. In case the national authority responsible for notified bodies determines that the notified body does not have the capability to support existing certificates issued, the manufacturer shall provide to the competent authority for devices within three months of the suspension or restriction, either the competent authority for in vitro diagnostic medical devices of the Member State in which the manufacturer of the device covered by the certificate is established, or another notified body confirm in writing **the written confirmation** that **another qualified notified body** that it is **temporarily** assuming the functions of the notified body to monitor and remain responsible for the certificates during the period of suspension or restriction.*

5a. *With the exception of certificates unduly issued, and where a notification has been withdrawn, the certificates shall remain valid for a period of nine months in the following circumstances:*

~~(b)~~ *in the case of restriction or withdrawal of a notification: for a period of three months after the restriction or withdrawal. The **where the** competent authority for in vitro diagnostic medical devices of the Member State in which the manufacturer **or the authorised representative** of the device covered by the certificate is established **has confirmed that there is no safety issue associated with the devices in question, and***  
*- **another notified body has confirmed in writing that it will assume immediate responsibilities for these products and will have completed assessment of the devices within twelve months, then***

- *the national competent authority of the member state where the manufacturer or authorised representative is established* may extend the *provisional* validity of the certificates for further periods of three months, which altogether may not exceed twelve months, ~~provided it is assuming the functions of the notified body during this period.~~

~~The authority or the notified body assuming the functions of the notified body affected by the change of notification shall immediately inform the Commission, the other Member States and the other notified bodies thereof.~~

### *Article 35*

#### *Challenge to the competence of notified bodies*

1. The Commission, ***in conjunction with the MDCG***, shall investigate all cases where concerns have been brought to its attention regarding the continued fulfilment by a notified body, ***or of one or more of its subsidiaries or subcontractors***, of the requirements set out in Annex VI or the obligations to which it is subject. ***It shall ensure that the concerned national authority responsible for notified bodies is informed and is given opportunity to investigate these concerns.*** ~~It may also commence such investigations on its own initiative.~~
2. The notifying Member State shall provide the Commission, on request, with all information regarding the notification of the notified body concerned.

- 2a. *The Commission in conjunction with the MDCG may initiate, as applicable, the assessment process described in Article 30(3) and (4) when there is reasonable concern about the ongoing compliance of a notified body or a subsidiary or subcontractor of the notified body with the requirements set out in Annex VI and the investigation of the national authority is not deemed to have fully addressed the concerns or upon request of the national authority. The reporting and outcome of this assessment process shall follow the principles of Article 30(5) and 30(6). Alternatively, depending on the severity of the issue, the Commission in conjunction with the MDCG may request that the national authority responsible for notified bodies allow for participation of up to two experts from the list established pursuant to Article 30a-in an on-site assessment as part of the planned monitoring and surveillance activities in accordance with Article 33 and as outlined in the annual plan described in paragraph 3 therein.*
3. Where the Commission ascertains that a notified body no longer meets the requirements for its notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including the suspension, restriction or withdrawal of the ~~notification~~ **designation** if necessary.

Where the Member State fails to take the necessary corrective measures, the Commission may, by means of implementing acts, suspend, restrict or withdraw the notification. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3). It shall notify the Member State concerned of its decision and update the database and list of notified bodies.

- 3a. *The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.*

Article 36

*Exchange Peer review and exchange of experience between national authorities responsible for notified bodies*

1. The Commission shall provide for the organisation of exchange of experience and coordination of administrative practice between the national authorities responsible for notified bodies under this Regulation. ***This shall address elements including:***
  - (a) ***Development of best practice documents relating to the activities of the national authority responsible for notified bodies;***
  - (b) ***Development of guidance documents for notified bodies in relation to the implementation of this Regulation;***
  - (c) ***Training and qualification of the experts referred to in Article 30a.***
  - (d) ***Monitoring of trends relating to changes to notified body designations and notifications and trends in certificate withdrawals and transfers between notified bodies;***
  - (e) ***Monitoring of the application and applicability of scope codes referred to in Article 31.4a;***
  - (f) ***Development of a mechanism for peer review between authorities and the Commission;***
  - (g) ***Methods of communication to the public on the monitoring and surveillance activities of authorities and the Commission on notified bodies for in vitro diagnostic medical devices.***
  
2. ***The national authorities responsible for notified bodies shall participate in a peer review every third year in accordance with the mechanism agreed in Article 36(1). These reviews shall normally be conducted during on-site joint assessments described in Article 30 but alternatively on a voluntary basis may take place as part of the national authority's monitoring activities in Article 33.***

3. *The Commission shall participate in the organisation and implementation of the peer review mechanism, including coordinating peer review. The Commission shall report on the Member States implementation of the requirements in Article 26, taking best practice in the Union into consideration.*

3a. *The Commission shall compile a report of the peer review for the national authority being reviewed. The report documenting the outcome of the peer-review shall be communicated to the Member State concerned and, with the consent of the national authority being reviewed, to all other Member States.*

*The Commission shall also compile an annual summary report of the peer review activities which shall be made publicly available.*

4. *The Commission may, by means of implementing acts, adopt measures setting out the modalities and associated documents for the peer review, and training and qualification mechanisms referred to in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).*

#### *Article 37*

##### *Coordination of notified bodies*

The Commission shall ensure that appropriate coordination and cooperation between notified bodies is put in place and operated in the form of a coordination group of notified bodies in the field of medical devices, including *in vitro* diagnostic medical devices.

The bodies notified under this Regulation shall participate in the work of that group.



*Article 38*

*Fees*

1. ~~The Member State where the bodies are established shall levy fees on applicant conformity assessment bodies and on notified bodies. These fees shall, wholly or partly, cover the costs relating to the activities exercised by the national authorities responsible for notified bodies **and by the joint assessment teams** in accordance with this Regulation.~~
  
2. ~~The Commission shall be empowered to adopt delegated acts in accordance with Article 85 setting out the structure and the level of the fees referred to in paragraph 1, taking into account the objectives of protection of human health and safety, support of innovation and cost effectiveness. Particular attention shall be paid to the interests of notified bodies that received a certificate delivered by the national accreditation body as referred to in Article 29(2) and notified bodies that are small and medium-sized enterprises as defined by Commission Recommendation 2003/361/EC.~~

# Chapter V

## Classification and conformity assessment

### Section 1 – Classification

#### *Article 39*

#### *Classification of in vitro diagnostic medical devices*

1. Devices shall be divided into classes A, B, C and D, taking into account their ~~intended~~ purpose ***intended by the manufacturer*** and inherent risks. Classification shall be carried out in accordance with the classification criteria set out in Annex VII.
2. Any dispute between the manufacturer and the notified body concerned, arising from the application of the classification criteria, shall be referred for a decision to the competent authority of the Member State where the manufacturer has his registered place of business. In cases where the manufacturer has no registered place of business in the Union and has not yet designated an authorised representative, the matter shall be referred to the competent authority of the Member State where the authorised representative referred to in the last indent of point (b) of Section 3.2. of Annex VIII has his registered place of business. ***Where the notified body concerned is located in a different Member State to the manufacturer, the competent authority shall adopt its decision after consultation with the competent authority of the Member State that designated the notified body.***

***The*** ~~At least 14 days prior to any decision,~~ the competent authority ***of the manufacturer*** shall notify the MDCG and the Commission of its ~~envisaged~~ decision.

3. ~~At The Commission may, at the~~ *a* request of a Member State ~~the Commission shall or on its own initiative~~ *after consulting the MDCG, decide*, by means of implementing acts, decide on the *following*:
- (a) application of the classification criteria set out in Annex VII to a given device, or category or group of devices, with a view to determining their classification;
  - (b) *that a device, or category or group of devices shall for reasons of public health based on new scientific evidence, or based on any information which becomes available in the course of the vigilance and market surveillance activities by way of derogation from the classification criteria set out in Annex VII, be reclassified.*
- 3a. *The Commission may also, on its own initiative and after consulting the MDCG, decide, by means of implementing acts, on the issues referred to in paragraph 3, points (a) and (b).*
- 3b. ~~Those~~ *The* implementing acts *referred to in paragraphs 3 and 3a* shall be adopted in accordance with the examination procedure referred to in Article 84(3).
4. ~~In order to ensure the uniform application of the classification criteria set out in Annex VII the light of technical progress and any information which becomes available in the course of the vigilance and market surveillance activities described in Articles 59 to 73, the Commission shall be empowered to~~ *may* adopt delegated *implementing* acts in accordance with Article ~~85~~ *84(3)* as regards the following:
- (a) ~~deciding that a device, or category or group of devices, should, by way of derogation from the classification criteria set out in Annex VII, be classified in another class;~~
  - (b) ~~amending or supplementing the classification criteria set out in Annex VII.~~

## Section 2 – Conformity assessment

### Article 40

#### Conformity assessment procedures

1. Prior to placing a device on the market, manufacturers shall undertake an assessment of the conformity of that device. The conformity assessment procedures are set out in Annexes VIII to X.
  - 1a. ***Prior to putting into service devices that are not placed on the market, with the exception of in-house devices manufactured pursuant to Article 4(5), manufacturers shall undertake an assessment of the conformity of that device. The conformity assessment procedures are set out in Annexes VIII to X.***
2. Manufacturers of devices classified as class D, other than devices for performance evaluation, shall be subject to a conformity assessment based on ~~full~~ quality ***management system*** assurance, ~~and design dossier examination~~ ***assessment of the technical documentation*** and batch verification, as specified in Annex VIII. Alternatively, the manufacturer may choose to apply a conformity assessment based on type examination as specified in Annex IX, coupled with a conformity assessment based on production quality assurance including batch verification, as specified in Annex X.

In addition, where a ***one or more*** reference ~~laboratory~~ ***laboratories*** is ***are*** designated in accordance with Article 78, the notified body performing the conformity assessment shall request ***one of these*** ~~that~~ reference ~~laboratory~~ ***laboratories*** to verify ***by laboratory testing the claimed performance and the*** compliance of the device with the applicable CFS, when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent, as specified in Section 5.4 of Annex VIII and in Section 3.5 of Annex IX. ***Laboratory tests performed by a reference laboratory shall in particular focus on analytical sensitivity using reference materials.***

For companion diagnostics ~~intended to be used to assess the patient eligibility for treatment with a specific medicinal product~~, the notified body shall consult ~~one of the~~ **concerned** competent ~~authorities~~ **authority** designated by the Member States in accordance with Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use or the European Medicines Agency (EMA), **as applicable**, in accordance with the procedures set out in Section 6.2 of Annex VIII and in Section 3.6 of Annex IX.

3. Manufacturers of devices classified as class C, other than devices for performance evaluation, shall be subject to a conformity assessment based on ~~full-quality~~ **management system** assurance as specified in Annex VIII, **except for its Chapter II**, with assessment of the ~~design documentation within the technical documentation on a representative basis of at least one device representative per generic device group~~. Alternatively, the manufacturer may choose to apply a conformity assessment based on type examination, as specified in Annex IX coupled with **a** conformity assessment based on production quality assurance, as specified in Annex X.

In addition, for devices for self-testing and near-patient testing, the manufacturer shall **follow the procedure for technical documentation assessment** ~~fulfil the supplementary requirements set out in Section 6.1 of Annex VIII or in Section 2 of Annex IX.~~

~~For~~ **In addition, for all** companion diagnostics ~~intended to be used to assess the patient eligibility to a treatment with a specific medicinal product~~, the notified body **shall follow the procedure for technical documentation assessment and** shall consult ~~one of the~~ **concerned** competent ~~authorities~~ **authority** designated by the Member States in accordance with Directive 2001/83/EC or the European Medicines Agency (EMA), **as applicable**, in accordance with the procedures set out in Section 6.2 of Annex VIII and in Section 3.6 of Annex IX.

4. Manufacturers of devices classified as class B, other than devices for performance evaluation, shall be subject to a conformity assessment based on full quality *management system* assurance, as specified in Annex VIII, *except for its Chapter II, with assessment of the technical documentation of at least one representative device for each category of devices.*

In addition, for devices for self-testing and near-patient testing, the manufacturer shall *follow the procedure for assessment of the technical documentation* fulfil the supplementary requirements set out in Section 6.1 of Annex VIII.

5. Manufacturers of devices classified as class A, other than devices for performance evaluation, shall declare the conformity of their products by issuing the EU declaration of conformity referred to in Article 15, after drawing up the technical documentation set out in Annex II.

However, if the devices ~~are intended for near-patient testing, or if they~~ are placed on the market in sterile condition ~~or have a measuring function~~, the manufacturer shall apply the procedures set out in Annex VIII or in Annex X. Involvement of the notified body shall be limited:

- (a) ~~in the case of devices for near-patient testing, to the requirements set out in Section 6.1 of Annex VIII,~~
  - (b) ~~in the case of devices placed on the market in sterile condition, to the aspects of manufacture concerned with *establishing*, securing and maintaining sterile conditions,~~
  - (c) ~~in the case of devices with a measuring function, to the aspects of manufacture concerned with the conformity of the devices with the metrological requirements.~~
6. ~~Manufacturers may choose to apply a conformity assessment procedure applicable to devices of a higher class than the device in question.~~
7. Devices *intended to be used in I performance evaluation studies, including devices* for performance evaluation shall be subject to the requirements set out in *Annex XII, and, if applicable*, Articles 48 to 58.

8. The Member State in which the notified body is established may determine that all or certain documents, including the technical documentation, audit, assessment and inspection reports, relating to the procedures referred to in paragraphs 1 to 6 shall be available in an official Union language(s) **determined by the Member State concerned**. Otherwise they shall be available in an official Union language acceptable to the notified body.
9. The Commission may, by means of implementing acts, specify the modalities and the procedural aspects with a view to ensuring harmonised application of the conformity assessment procedures by the notified bodies, for any of the following aspects:
- the frequency and the sampling basis of the assessment of ~~the design documentation~~ ~~within~~ the technical documentation on a representative basis as set out in Sections 3.3.(c) and 4.5 of Annex VIII, in the case of devices classified as class C ;
  - the minimum frequency of unannounced ~~factory inspections~~ **on-site audits** and sample checks to be conducted by notified bodies in accordance with Section 4.4 of Annex VIII, taking into account the risk-class and the type of device;
  - the frequency of samples of the manufactured devices or batches of devices classified as class D to be sent to a reference laboratory designated under Article 78 in accordance with Section 5.7 of Annex VIII and Section 5.1 of Annex X, or
  - the physical, laboratory or other tests to be carried out by notified bodies in the context of sample checks, **assessment of technical documentation** ~~design dossier examination~~ and type examination in accordance with Sections 4.4 and 5.3 of Annex VIII and Sections 3.2 and 3.3 of Annex IX.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

10. In the light of technical **and scientific** progress and any information which becomes available in the course of the designation or monitoring of notified bodies set out in Articles 26 to 38, or of the vigilance and market surveillance activities described in Articles 59 to 73, the Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing **updating** the conformity assessment procedures set out in Annexes VIII to X.

## Article 41

### *Involvement of notified bodies*

1. Where the conformity assessment procedure requires the involvement of a notified body, the manufacturer may apply to a notified body of his choice, provided that the body is notified for the conformity assessment activities, the conformity assessment procedures and the devices concerned. An application may not be lodged in parallel with ~~more than one~~ **another** notified body for the same conformity assessment ~~activity~~ **procedure**.
2. The notified body concerned shall inform the other notified bodies of any manufacturer who withdraws his application prior to the notified body's decision regarding the conformity assessment, **by means of the electronic system referred to in Article 23**.
- 2a. Manufacturers shall declare whether they have withdrawn an application with another notified body prior to the decision of that notified body or provide information about any previous application for the same type that has been refused by another notified body.**
3. The notified body may require any information or data from the manufacturer ~~which is~~ necessary in order to properly conduct the chosen conformity assessment procedure.
4. Notified bodies and the personnel of notified bodies shall carry out their conformity assessment activities with the highest degree of professional integrity and the requisite technical **and scientific** competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups with an interest in the results of those activities.



## Article 42

### *Mechanism for scrutiny of certain conformity assessments*

1. Notified bodies shall notify the **competent authorities of certifications they have granted** ~~Commission of applications for conformity assessments~~ for devices classified as class D, with the exception of applications to supplement or renew existing certificates. ~~The~~ **Such** notification shall **take place automatically through the electronic system referred to in Article 25 and shall** be accompanied by the ~~draft~~ instructions for use referred to in Section 17.3 of Annex I, ~~and the draft summary of safety and performance referred to in Article 24,~~ **the assessment report by the notified body, and, where applicable, the laboratory tests by the reference laboratory according to Article 40(2) second subparagraph.** ~~In its notification the notified body shall indicate the estimated date by which the conformity assessment is to be completed. The Commission shall immediately transmit the notification and the accompanying documents to the MDCG.~~

*A competent authority and, where applicable, the Commission may, based on reasonable concerns, apply further procedures according to articles 33, 33a, 34, 35, 67 and, when deemed necessary, take appropriate measures according to Article 68.*

2. ~~Within 28 days of receipt of the information referred to in paragraph 1, the MDCG may request the notified body to submit a summary of the preliminary conformity assessment prior to issuing a certificate. Upon suggestion by any of its members or by the Commission, the MDCG shall decide on making such request in accordance with the procedure set out in Article 78(4) of Regulation [Ref. of future Regulation on medical devices]. In its request the MDCG shall indicate the scientifically valid health reason for having selected the specific file for submission of a summary of the preliminary conformity assessment. When selecting a specific file for submission, the principle of equal treatment shall be duly taken into account.~~

~~Within 5 days after receipt of the request by the MDCG, the notified body shall inform the manufacturer thereof.~~

3. ~~The MDCG may submit comments on the summary of the preliminary conformity assessment at the latest 60 days after submission of this summary. Within that period and at the latest 30 days after submission, the MDCG may request the submission of additional information that for scientifically valid grounds are necessary for the analysis of the notified body's preliminary conformity assessment. This may include a request for samples or an on-site visit to the manufacturer's premises. Until submission of the additional information requested, the period for comments referred to in the first sentence of this subparagraph shall be suspended. Subsequent requests for additional information from the MDCG shall not suspend the period for the submission of comments.~~
4. ~~The notified body shall give due consideration to any comments received in accordance with paragraph 3. It shall convey to the Commission an explanation of how they have been taken into consideration, including any due justification for not following the comments received, and its final decision regarding the conformity assessment in question. The Commission shall immediately transmit this information to the MDCG.~~
5. ~~Where deemed necessary for the protection of patient safety and public health, the Commission may determine, by means of implementing acts, specific categories or groups of devices, other than devices classified as class D, to which paragraphs 1 to 4 shall apply during a predefined period of time. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).~~

~~Measures pursuant to this paragraph may be justified only by one or more of the following criteria:~~

- (a) ~~the novelty of the device or of the technology on which it is based and the significant clinical or public health impact thereof;~~
- (b) ~~an adverse change in the risk-benefit profile of a specific category or group of devices due to scientifically valid health concerns in respect of components or source material or in respect of the impact on health in case of failure;~~

- (c) an increased rate of serious incidents reported in accordance with Article 59 in respect of a specific category or group of devices;
  - (d) significant discrepancies in the conformity assessments carried out by different notified bodies on substantially similar devices;
  - (e) public health concerns regarding a specific category or group of devices or the technology on which they are based.
6. The Commission shall make a summary of the comments submitted in accordance with paragraph 3 and the outcome of the conformity assessment procedure accessible to the public. It shall not disclose any personal data or information of commercially confidential nature.
7. The Commission shall set up the technical infrastructure for the data-exchange by an electronic means between notified bodies and MDCG for the purposes of this Article.
8. The Commission, by means of implementing acts, may adopt the modalities and the procedural aspects concerning the submission and analysis of the summary of the preliminary conformity assessment in accordance with paragraphs 2 and 3. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

#### *Article 43*

#### *Certificates*

1. The certificates issued by the notified bodies in accordance with Annexes VIII, IX and X shall be in an official Union language determined by the Member State in which the notified body is established or otherwise in an official Union language acceptable to the notified body. The minimum content of the certificates is set out in Annex XI.

2. The certificates shall be valid for the period they indicate, which shall not exceed five years. On application by the manufacturer, the validity of the certificate may be extended for further periods, each not exceeding five years, based on a re-assessment in accordance with the applicable conformity assessment procedures. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid.
  - 2a. *Notified bodies may impose restrictions to the intended purpose of a device to certain numbers or groups of patients or require manufacturers to undertake specific post-market performance follow-up studies pursuant to Part B of Annex XII.*
3. Where a notified body finds that requirements of this Regulation are no longer met by the manufacturer, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or impose any restrictions on it unless compliance with such requirements is ensured by appropriate corrective **action measures** taken by the manufacturer within an appropriate deadline set by the notified body. The notified body shall give the reasons for its decision.
4. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process information on certificates issued by notified bodies. The notified body shall enter into ~~the~~ **this** electronic system **information** regarding certificates issued, including amendments and supplements, and regarding suspended, reinstated, withdrawn or refused certificates and restrictions imposed on certificates. This information shall be accessible to the public.
5. In the light of technical progress, the Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing the minimum content of the certificates set out in Annex XI.

*Article 44*

*Voluntary change of notified body*

1. In cases where a manufacturer terminates his contract with a notified body and enters into a contract with another notified body in respect of the conformity assessment of the same device, the modalities of the change of notified body shall be clearly defined in an agreement between the manufacturer, the outgoing notified body, ***where practicable***, and the incoming notified body. This agreement shall address at least the following aspects:
  - (a) the date of invalidity of certificates issued by the outgoing notified body;
  - (b) the date until which the identification number of the outgoing notified body may be indicated in the information supplied by the manufacturer, including any promotional material;
  - (c) the transfer of documents, including confidentiality aspects and property rights;
  - ~~(d) the date as of which the incoming notified body assumes full responsibility for the conformity assessment tasks.~~
  - (e) the date after which the conformity assessment tasks and the full responsibility for the manufacturer's products including products assessed by the outgoing Notified body is assigned to the incoming notified body;***
  - (f) the last serial number or batch code/lot number for which the outgoing notified body is responsible.***
  
2. On their date of invalidity, the outgoing notified body shall withdraw the certificates it has issued for the device concerned.

## Article 45

### *Derogation from the conformity assessment procedures*

1. By way of derogation from Article 40, any competent authority may authorise, on duly justified request, the placing on the market or putting into service, within the territory of the Member State concerned, of a specific device for which the procedures referred to in Article 40 have not been carried out and use of which is in the interest of public health or patient safety **or health**.
2. The Member State shall inform the Commission and the other Member States of any decision to authorise the placing on the market or putting into service of a device in accordance with paragraph 1 where such authorisation is granted for use other than for a single patient.
3. ~~Upon request by a Member State and where this is in the interest of~~ **Following a notification pursuant to paragraph 2, the Commission, in exceptional cases relating to** a public health or patients safety **or health**, ~~in more than one Member State, the Commission~~ may, by means of implementing acts, extend for a determined period of time the validity of an authorisation granted by a Member State in accordance with paragraph 1 to the territory of the Union and set the conditions under which the device may be placed on the market or put into service. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 84(4).

*Article 46*

*Certificate of free sale*

1. For the purpose of export and upon request by a manufacturer ***or an authorised representative***, the Member State in which the manufacturer ***or the authorised representative*** has its registered place of business shall issue a certificate of free sale declaring that the manufacturer ***or the authorised representative, as applicable***, is ~~properly~~ established and that the device in question bearing the CE-marking in accordance with this Regulation may be ~~legally~~ marketed in the Union. The certificate of free sale shall ~~be valid for the period indicated on it which shall not exceed five years and shall not exceed the validity of the~~ ***set out the identification of the device in the electronic system set up under Article 25. Where a notified body has issued a certificate referred to in Article 43, the certificate of free sale shall set out the number of the certificate*** ~~issued for the device in question.~~
  
2. The Commission may, by means of implementing acts, establish a model for certificates of free sale taking into account international practice as regards the use of certificates of free sale. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 84(2).

## Chapter VI

### ~~Clinical evidence~~ *Performance evaluation and performance studies*

#### *Article 47*

##### *General requirements regarding ~~clinical evidence~~ Performance evaluation*

1. ~~The demonstration of conformity with the general safety and performance requirements set out in Annex I, under normal conditions of use, shall be based on clinical evidence.~~

*Confirmation of conformity with the requirements, in particular those concerning the performance characteristics referred to in Section I and Section II.6 of Annex I and where applicable relevant requirements of Annex IIa under the normal conditions of the intended use of the device, and the evaluation of the interference(s) and cross-reaction(s) and of the acceptability of the benefit/risk ratio referred to in Sections 1 and 5 of Annex I, shall be based on scientific validity, analytical and clinical performance data providing sufficient clinical evidence.*

*The manufacturer shall specify and justify the level of the clinical evidence necessary to demonstrate compliance with the relevant essential requirements on safety and performance which shall be appropriate to the characteristics of the device and its intended purpose.*

*To that end, manufacturers shall plan, conduct and document a performance evaluation in accordance with this Article and with Part A of Annex XII.*

2. The clinical evidence shall support the intended purpose of the device as stated by the manufacturer *and be based on a continuous process of performance evaluation, following a performance evaluation plan.*



3. *A performance evaluation shall follow a defined and methodologically sound procedure for the demonstration of the following, in accordance with the principles set out in this Article and with Annex XII:*
- (a) scientific validity;*
  - (b) analytical performance;*
  - (c) clinical performance.*

*The data and conclusions drawn from the assessment of these elements shall constitute the clinical evidence for the device. The clinical evidence shall scientifically demonstrate that the intended clinical benefit(s) and safety will be achieved according to the state of the art in medicine. The clinical evidence derived from the performance evaluation shall include provide scientifically valid assurance, all the information supporting the scientific validity of the analyte, the analytical performance and, where applicable, the clinical performance of the device, as described in Section 1 of Part A of Annex XII that the relevant general safety and performance requirements set out in Annex I, under normal conditions of use, are fulfilled.*

4. ~~Where demonstration of conformity with the general safety and performance requirements based on clinical performance data or parts thereof is not deemed appropriate, adequate justification for any such exception shall be given based on the results of the manufacturer's risk management and on consideration of the characteristics of the device and, in particular, its intended purpose(s), the intended performance and the claims of the manufacturer. The adequacy of demonstration of conformity with the general safety and performance requirements based on the results of analytical performance evaluation alone shall be duly substantiated in the technical documentation referred to in Annex II.~~

5. The scientific validity data, the analytical performance data and, ~~where applicable,~~ the clinical performance data **and their assessment** shall be summarised **documented in reports** as part of a ~~clinical evidence~~ **performance evaluation** report referred to in Section 3 **1.4** of Part A of Annex XII, **that shall include the clinical evidence derived from it**. The ~~clinical evidence~~ **performance evaluation** report shall be ~~included or fully referenced in~~ **part of** the technical documentation referred to in Annex II relating to the device concerned.
6. The ~~clinical evidence~~ **performance evaluation** and its documentation shall be updated throughout the life cycle of the device concerned with data obtained from implementation of the manufacturer's **post-market performance follow-up plan, as part of the** post-market surveillance plan referred to in Article 8(67).

***The performance evaluation report for devices classified as class C and D shall be updated when necessary, but at least annually with these data. The summary of safety and performance referred to in Article 24(1) shall be updated as soon as possible, where necessary.***

7. The manufacturer shall ensure that ~~the~~ a device **used** for performance evaluation complies with the general requirements of this Regulation apart from the aspects covered by the performance evaluation and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the patient, user and other persons.

~~The manufacturer shall undertake to keep available to the competent authorities and the EU reference laboratories the documentation allowing an understanding of the design, manufacture and performances of the device, including its expected performance, so as to allow assessment of conformity with the requirements of this Regulation. This documentation shall be kept for at least five years after the performance evaluation of the device in question has ended.~~

8. *Where necessary to ensure the uniform application of Annex XII the Commission may, having due regard to technical and scientific progress, adopt implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).*

#### *Article 48*

##### *General requirements regarding ~~clinical~~ performance studies*

1. ~~Clinical~~ **Performance** ~~performance~~ studies shall be subject to *the provisions of Articles 48 to 58 of this Regulation* if they are conducted *under* ~~for~~ one or more of the following *conditions* purposes:
- (a) *where invasive sample taking is done only for the purpose of the performance study* ~~to verify that, under normal conditions of use, the devices are designed, manufactured and packaged in such a way that they are suitable for one or more of the specific purposes of an *in vitro* diagnostic medical device referred to in number (2) of Article 2, and achieve the performance intended as specified by the manufacturers;~~
  - (b) *where it concerns an interventional clinical performance study as defined in Article 2(37)* ~~to verify that devices achieve the intended benefits to the patient as specified by the manufacturer;~~
  - (c) *where the conduct of the study involves additional invasive procedures or other risks for the subjects of the studies* ~~to determine any limits to the performance of the devices, under normal conditions of use;~~
  - (d) *in case of performance studies involving companion diagnostics.*
2. **Performance** Clinical performance studies shall be performed in circumstances similar to the normal conditions of use of the device.

3. Where the sponsor *of a performance study* is not established in the Union, ~~he~~ *that sponsor* shall ensure that a *natural or legal person* ~~contact person~~ is established in the Union *as its legal representative*. ~~That contact person~~ *Such legal representative shall be responsible for ensuring compliance with the sponsor's obligations pursuant to this Regulation, and* shall be the addressee for all communications with the sponsor provided for in this Regulation. Any communication to that ~~contact person~~ *legal representative* shall be ~~considered as~~ *deemed to be a* communication to the sponsor.

*Member States may choose not to apply subparagraph above as regards performance studies to be conducted solely on their territory, or on their territory and the territory of a third country, provided that they ensure that the sponsor establishes at least a contact person on their territory in respect of that performance study who shall be the addressee for all communications with the sponsor provided for in this Regulation.*

4. All ~~clinical~~ performance studies shall be designed and conducted in a way that the rights, safety, *dignity* and well-being of the subjects participating in such ~~clinical~~ performance studies are protected and *prevail over all other interests and* ~~that the clinical data generated in the clinical performance study~~ are going to be *scientifically valid*, reliable and robust.

*Performance studies shall be subject to scientific and ethical assessment. The ethical review shall be performed by an ethics committee in accordance with the law of the Member State concerned. Member States shall ensure that the timelines and procedures for the review by the ethics committees are compatible with the timelines and procedures set out in this Regulation for the assessment of the application for authorisation of a performance study.*

5. All ~~clinical~~ performance studies shall be designed, conducted, recorded and reported in accordance with Section 2 of Annex XII.

~~6. For interventional clinical performance studies, as defined in number (37) of Article 2, and for other clinical performance studies, where the conduct of the study, including specimen collection, involves invasive procedures or other risks for the subjects of the studies, the requirements set out in Articles 49 to 58 and in Annex XIII shall apply, in addition to the obligations laid down in this Article.~~

**6a. A performance study according to paragraph 1 may be conducted only where all of the following conditions are met:**

- (a) the performance study was subject to an authorisation by a Member State(s) concerned, in accordance with this Regulation, unless otherwise stated;**
- (b) an independent ethics committee, set up according to national law, has issued an opinion on the planned performance study which is not negative and which, in accordance with the law of the Member State concerned, is valid for that entire Member State;**
- (c) the sponsor or its legally designated representative or a contact person pursuant to paragraph 3 is established in the Union;**
- (ca) vulnerable population and subjects are appropriately protected according to relevant national provisions;**
- (d) the foreseeable risks and inconveniences to the subject are medically justifiable when weighed against the device's potential relevance for the subjects and/or medicine;**
- (e) the subject or, where the subject is not able to give informed consent, his or her legally designated representative has given informed consent, according to Article 29 of Regulation (EU) no 536/2014 on clinical trials on medicinal products for human use, and repealing directive 2001/20/EC ;**
- (f) the rights of the subject to physical and mental integrity, to privacy and to the protection of the data concerning him or her in accordance with Directive 95/46/EC are safeguarded;**
- (h) where appropriate, biological safety testing reflecting the latest scientific knowledge or any other test deemed necessary in the light of the device's intended purpose has been conducted;**

- (i) in case of clinical performance studies, the analytical performance has been demonstrated, taking into consideration the state of the art;*
  - (ia) in case of interventional clinical performance studies, the analytical performance and scientific validity has been demonstrated, taking into consideration the state of the art;*
  - (j) the technical safety of the device with regard to its use has been proven, taking into consideration the state of the art as well as provisions in the field of occupational safety and accident prevention;*
  - (k) the requirements of Annex XIII are fulfilled.*
7. *Any subject may, without any resulting detriment, withdraw from the performance study at any time by revoking his or her informed consent. Without prejudice to Directive 95/46/EC, the withdrawal of the informed consent shall not affect the activities already carried out and the use of data obtained based on informed consent before the withdrawal.*
8. *The investigator shall be a person, as defined in national law, following a profession which is recognised in the Member State concerned, as qualifying for an investigator because of the necessary scientific knowledge and experience in patient care. Other individuals involved in conducting a performance study shall be suitably qualified by education, training or experience in the relevant medical field and in clinical research methodology, to perform their tasks.*
9. *The facilities where the performance study involving subjects is to be conducted shall be similar to the facilities of the intended use and suitable for the performance study.*

#### *Article 48b*

##### *Protection of vulnerable subjects; emergency situations*

*In order to specifically protect the rights, safety, dignity and well-being of vulnerable subjects in performance studies, Member States shall take appropriate measures, concerning performance studies*

- (a) on minors,*
- (b) on incapacitated subjects,*
- (c) on pregnant and breastfeeding women,*
- (d) in emergency situations, and/or*
- (e) on persons in residential care institutions, persons performing mandatory military service, persons deprived of liberty, persons who, due to a judicial decision, cannot take part in performance studies.*

#### *Article 48c*

##### *Damage compensation*

- 1. Member States shall ensure that systems for compensation for any damage suffered by a subject resulting from participation in a performance study conducted on their territory are in place in the form of insurance, a guarantee, or a similar arrangement that is equivalent as regards its purpose and which is appropriate to the nature and the extent of the risk.*
- 2. The sponsor and the investigator shall make use of the system referred to in paragraph 1 in the form appropriate for the Member State concerned where the performance study is conducted.*

*Article 49*

*Application for interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies*

1. ~~Before making the first application, the sponsor shall procure from the electronic system referred to in Article 51 a single identification number for a clinical performance study conducted in one site or multiple sites, in one or more than one Member State. The sponsor shall use this single identification number when registering the clinical performance study in accordance with Article 50.~~
  
2. The sponsor of a ~~clinical~~ performance study shall ***enter and submit by means of the electronic system referred to in Article 51*** an application to the Member State(s) in which the study is to be conducted accompanied by the documentation referred to in ***Chapter I of Annex XII and in Annex XIII. The electronic system referred to in Article 51 shall generate a union wide unique single identification number for this performance study which shall be used for all relevant communication in relation to the performance study concerned.*** Within ~~six~~ ***ten*** days after receipt of the application, the Member State concerned shall notify the sponsor whether the ~~clinical~~ performance study falls within the scope of this Regulation and whether the application is complete.

~~Where the Member State has not notified the sponsor within the time period referred to in the first subparagraph, the clinical performance study shall be considered as falling within the scope of this Regulation and the application shall be considered complete.~~



3. Where the Member State finds that the ~~clinical~~ performance study applied for does not fall within the scope of this Regulation or that the application is not complete, it shall inform the sponsor thereof and shall set a maximum of ~~six~~ **thirty** days for the sponsor to comment or to complete the application.

Where the sponsor has not provided comments nor completed the application within the time-period referred to in the first subparagraph, the application shall be ~~considered as withdrawn~~ **deemed to have lapsed. Where the sponsor considers that the application falls under the scope of the regulation and/or is complete but the competent authority does not agree, the application shall be considered as rejected. That Member States shall provide for an appeal procedure in respect of such refusal.**

~~The~~ Where the Member State ~~has~~ **shall notify** ~~not notified~~ the sponsor according to paragraph ~~2~~ within ~~five~~ **three** days following receipt of the comments or of the ~~completed application~~ **requested additional information, whether** the clinical performance study ~~is~~ shall be considered as falling within the scope of this Regulation and the application shall be ~~considered~~ **is** complete .

4. For the purposes of this Chapter, the date on which the sponsor is notified in accordance with paragraphs 2 **or** 3 shall be the validation date of the application. ~~Where the sponsor is not notified, the validation date shall be the last day of the time periods referred to in paragraphs 2 and 3.~~ **The concerned Member State may also extend the period referred to in paragraph 2 and 3 each by a further 5 days.**
  - 4a. **In the period during which the application is being assessed the Member State may request, additional information from the sponsor. The expiry of the deadline pursuant to the second indent of paragraph 5(b) shall be suspended from the date of the first request until such time as the additional information has been received.**

5. The sponsor may start the clinical performance study in the following circumstances:
- (a) in the case of ~~devices for performance evaluation classified as class C or D, as soon as~~ *studies according to Article 48(1)(a) and where the specimen collection does not represent a major clinical risk to the subject of the study, unless otherwise stated by national provisions, immediately after the validation date of application described in paragraph 4, provided that the competent ethics committee in the Member State concerned has notified the sponsor of its approval issued an opinion which is not negative and which, in accordance with the law of the Member State concerned, is valid for that entire Member State;*
  - (b) in the case of ~~devices for performance evaluation classified as class A or B immediately after the date of application, provided that the Member State concerned has so decided and that evidence is provided that the rights, safety and well-being of the subjects to the~~ *clinical performance study are protected performance studies according to Article 48(1)(b), (c), (d) and (e) or performance studies other than those referred to in subparagraph (a):*
    - *as soon as the Member State concerned has notified the sponsor of its authorisation and provided that the competent ethics committee in the Member State concerned has issued an opinion which is not negative and which, in accordance with the law of the Member State concerned, is valid for that entire Member State; or*
    - *after the expiry of 45 days after the validation date referred to in paragraph 4, unless the Member State concerned has notified the sponsor within that period of its refusal and provided that the ethics committee in the Member State concerned has issued an opinion which is not negative and which, in accordance with the law of the Member State concerned, is valid for that entire Member State.*

*The Member State concerned may also extend the period referred to in the previous sub-paragraph by a further 20 days for the purpose of consulting with experts.*

(e) ~~after the expiry of 35 days after the validation date referred to in paragraph 4, unless the Member State concerned has notified the sponsor within that period of its refusal based on considerations of public health, patient safety or public policy.~~

6. ~~Member States shall ensure that the persons assessing the application do not have conflicts of interest and that they are independent of the sponsor, the institution of the study site(s) and the investigators involved, as well as free of any other undue influence.~~

~~Member States shall ensure that the assessment is done jointly by a reasonable number of persons who collectively have the necessary qualifications and experience. In the assessment, the view of at least one person whose primary area of interest is non-scientific shall be taken into account. The view of at least one patient shall be taken into account.~~

7. ~~The Commission shall be empowered to *may* adopt delegated **implementing** acts in accordance with Article 85 **84(3)** amending or supplementing, in the light of technical progress and global regulatory developments, ***in order to assure the uniform application of*** the requirements for the documentation to be submitted with the application for the clinical performance study that is laid down in Chapter I of Annex XIII.~~

#### *Article 49a*

##### *Assessment by Member States*

1. ***Member States shall ensure that the persons validating and assessing the application, or deciding on it, do not have conflicts of interest, are independent of the sponsor, the investigators involved and of persons or legal persons financing the performance study, as well as free of any other undue influence.***
2. ***Member States shall ensure that the assessment is done jointly by a reasonable number of persons who collectively have the necessary qualifications and experience.***

3. *Member States shall assess whether the performance study is designed in such a way that potential remaining risks to subjects or third person, after risk minimization, are justified, when weighed against the clinical benefits to be expected. They shall examine, under consideration of applicable Common Specifications or harmonized standards, in particular:*
- (a) the demonstration of compliance of the device(s) for performance evaluation with the applicable general safety and performance requirements, apart from the aspects covered by the performance study and whether, with regard to these aspects, every precaution has been taken to protect the health and safety of the subjects. This includes, in case of performance studies, the evaluation of the analytical performance, and in case of interventional clinical performance studies, the evaluation of the analytical performance, clinical performance and scientific validity, taking into consideration the state of the art;*
  - (b) whether the risk-minimisation solutions employed by the sponsor are described in harmonised standards and, in those cases where the sponsor does not use harmonised standards, the equivalence of the level of protection to harmonised standards;*
  - (c) the plausibility of the measures planned for the safe installation, putting into service and maintenance of the device for performance evaluation;*
  - (d) the reliability and robustness of the data generated in the performance study, taking account of statistical approaches, design of the performance study and methodological aspects (including sample size, and comparator ~~and endpoints~~);*
  - (da) the requirements of Annex XIII are met.*
4. *Member States may refuse the authorisation of the performance study if:*
- (a) the performance study does not fall within the scope of this Regulation;*
  - (b) the application submitted according to Article 49 paragraph 3 remains incomplete;*
  - (c) an ethics committee has issued a negative opinion which, in accordance with the law of the Member State concerned, is valid for that entire Member State;*
  - (ca) the device or the submitted documents, especially the performance study plan and the investigator's brochure, do not correspond to the state of scientific knowledge, and the performance study, in particular, is not suitable to provide evidence for the safety, performance characteristics or benefit of the device on patients, or*

- (d) the requirements of Article 48 are not met, or*
- (e) any assessment according to paragraph 3 is negative.*

#### *Article 49b*

##### *Conduct of a performance study*

- 1. The sponsor and the investigator shall ensure that the performance study is conducted in accordance with the approved performance study plan.*
- 2. In order to verify that the rights, safety and well-being of subjects are protected, that the reported data are reliable and robust, and that the conduct of the performance study is in compliance with the requirements of this Regulation, the sponsor shall adequately monitor the conduct of a performance study. The extent and nature of the monitoring shall be determined by the sponsor on the basis of an assessment that takes into consideration all characteristics of the performance study including the following characteristics:
  - (a) the objective and methodology of the performance study and*
  - (b) the degree of deviation of the intervention from normal clinical practice.**
- 3. All performance study information shall be recorded, processed, handled, and stored by the sponsor or investigator, as applicable, in such a way that it can be accurately reported, interpreted and verified while the confidentiality of records and the personal data of the subjects remain protected in accordance with the applicable law on personal data protection.*
- 4. Appropriate technical and organisational measures shall be implemented to protect information and personal data processed against unauthorised or unlawful access, disclosure, dissemination, alteration, or destruction or accidental loss, in particular where the processing involves the transmission over a network.*

**64a. Member States shall inspect on an appropriate level performance study site(s) to check that performance study are conducted according to the requirements of this Regulation and to the approved investigation plan.**

**5. The sponsor shall establish a procedure for emergency situations which enables the immediate identification and, where necessary, an immediate recall of the devices used in the study.**

#### *Article 50*

##### *Registration of interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies*

1. Before commencing the clinical performance study, the sponsor shall enter in the electronic system referred to in Article 51 the following information regarding the clinical performance study:
  - (a) the single identification number of the clinical performance study;
  - (b) the name and contact details of the sponsor and, if applicable, his contact person established in the Union;
  - (c) the name and contact details of the natural or legal person responsible for the manufacture of the device for performance evaluation, if different from the sponsor;
  - (d) the description of the device for performance evaluation;
  - (e) the description of the comparator(s), if applicable;
  - (f) the purpose of the clinical performance study;
  - (g) the status of the clinical performance study.
  
2. Within one week of any change occurring in relation to the information referred to in paragraph 1, the sponsor shall update the relevant data in the electronic system referred to in Article 51.

3. ~~The information shall be accessible to the public, through the electronic system referred to in Article 51 unless, for all or parts of that information, confidentiality of the information is justified on any of the following grounds:~~
- ~~(a) protection of personal data in accordance with Regulation (EC) No 45/2001,~~
  - ~~(b) protection of commercially sensitive information,~~
  - ~~(c) effective supervision of the conduct of the clinical performance study by the Member State(s) concerned.~~
4. ~~No personal data of subjects participating in the clinical performance study shall be accessible to the public.~~

#### *Article 51*

##### *Electronic system on interventional clinical performance studies and other ~~clinical~~ performance studies involving risks for the subjects of the studies*

1. The Commission shall, in collaboration with the Member States, set up, ~~and~~ manage ***and maintain*** an electronic system on interventional clinical performance studies and other ~~clinical~~ performance studies involving risks for the subjects of the studies:
- (aa)*** to create the single identification numbers for such ~~clinical~~ performance studies;
  - (ab)*** ***to be used as an entry point for the submission of all applications for performance studies*** referred to in Article 49(12), ***52, 53, 56*** ~~and to collate and process the following information:~~ ***and for all other submission of data, or processing of data in this context;***
  - ~~(a) the registration of clinical performance studies in accordance with Article 50;~~
  - (b)*** ***for*** the exchange of information ***relating to performance studies in accordance with this Regulation*** between the Member States and between them and the Commission ~~in accordance with Article 54;~~ ***including those according to Article 49 a and 54;***
  - ~~(c) the information related to clinical performance studies conducted in more than one Member State in case of a single application in accordance with Article 56;~~
  - (ca)*** ***for information by the sponsor according to Article 55;***

- (d) ***for reporting*** ~~the reports on serious adverse events and device deficiencies~~ ***and related updates*** referred to in Article 57(2) ~~in case of single application in accordance with Article 56.~~
2. When setting up the electronic system referred in paragraph 1, the Commission shall ensure that it is interoperable with the EU database for clinical trials on medicinal products for human use set up in accordance with Article [...] of Regulation (EU) No [Ref. of future Regulation on clinical trials] ***536/2014 as concerns performance evaluation studies of companion diagnostics.*** ~~With the exception of the information referred to in Article 50, the information collated and processed in the electronic system shall be accessible only to the Member States and to the Commission.~~
- 2a. Within one week of any change occurring in relation to the information referred to in paragraph 1 or in Article 49(2), the sponsor shall update the relevant data in the electronic system referred to in this Article. The Member State concerned shall be notified of the update and the changes to the documents shall be clearly identifiable.***
3. ~~The Commission shall be empowered to adopt delegated acts in accordance with Article 85 determining which other information regarding clinical performance studies collated and processed in the electronic system shall be publicly accessible to allow interoperability with the EU database for clinical trials on medicinal products for human use set up by Regulation (EU) No [Ref. of future Regulation on clinical trials]. Article 50 (3) and (4) shall apply.~~
4. ***The information referred to in paragraph 1 shall, except the information referred to in point b, which shall only be accessible to the Member States and the Commission, shall be accessible to the public, through the electronic system referred to in Article 51, unless, for all or parts of that information, confidentiality of the information is justified on any of the following grounds:***
- (a) protection of personal data in accordance with Regulation (EC) No 45/2001,***



- (b) *protection of commercially confidential information, especially in the investigators brochure, in particular through taking into account the status of the conformity assessment for the device, unless there is an overriding public interest in disclosure,*
- (c) *effective supervision of the conduct of the clinical performance study by the Member State(s) concerned.*

4a. *No personal data of subjects participating in interventional clinical performance studies and other performance studies involving risks for the subjects of the studies shall be publicly available.*

4b. *The user interface of the electronic system referred to in this Article shall be available in all official languages of the Union.*

#### *Article 52*

*Interventional clinical performance studies and other ~~clinical~~ performance studies involving risks for the subjects of the studies with devices authorised to bear the CE marking*

1. Where a ~~clinical~~ performance study is to be conducted to further assess devices which are authorised in accordance with Article 40 to bear the CE marking and within its intended purpose referred to in the relevant conformity assessment procedure, hereinafter referred to as ‘post-market *performance* follow-up ~~performance~~ study’, the sponsor shall notify the Member States concerned at least 30 days prior to their commencement if the study would submit subjects to additionally invasive or burdensome procedures. ***The notification shall be made by means of the electronic system referred to in Article 51. It shall be accompanied by the documentation referred to in Chapter I of Annex XII and in Annex XIII. Article 48 paragraph 6a points (b) to (h) and (k), Articles 48(1) to (5), 50, 53, 54(1) and 55(1), the first subparagraph of Article 55(2), Article 57(6) and the relevant provisions of Annexes XII and XIII shall apply.***

2. If the aim of the ~~clinical~~ performance study regarding a device which is authorised in accordance with Article 40 to bear the CE marking is to assess such device for a purpose other than that referred to in the information supplied by the manufacturer in accordance with Section 17 of Annex I and in the relevant conformity assessment procedure, Articles 48 to 58 shall apply.

### *Article 53*

#### *Substantial modifications to interventional clinical performance studies and other ~~clinical~~ performance studies involving risks for the subjects of the studies*

1. If the sponsor ***intends to*** introduces modifications to a ~~clinical~~ performance study that are likely to have a substantial impact on the safety, ***health*** or rights of the subjects or on the robustness or reliability of the ~~clinical~~ data generated by the study, he shall notify ***by means of the electronic system referred to in Article 51*** the Member State(s) concerned of the reasons for and the content of those modifications. The notification shall be accompanied by an updated version of the relevant documentation referred to in Annex XIII ***in which changes shall be clearly identifiable.***
2. The sponsor may implement the modifications referred to in paragraph 1 at the earliest 380 days after notification, unless the Member State concerned has notified the sponsor of its refusal based on ***Article 49a paragraph 4 or*** considerations of public health, ***subject and user*** ~~patient~~ safety or ***health***, ***of*** public policy ***or the ethics committee concerned has issued a negative opinion which is in accordance with the law of that Member State, is valid for that entire Member State.***
3. ***The Member State(s) concerned may extend the period referred to in paragraph 2 by a further 7 days, for the purpose of consulting with experts.***

Article 54

~~Information~~ **Corrective measures to be taken by Member States and information exchange**  
between Member States on interventional clinical performance studies and other  
~~clinical~~ performance studies involving risks for the subjects of the studies

**0a. Where a Member State concerned has grounds for considering that the requirements set out in this Regulation are no longer met, it may at least take the following measures on its territory:**

- (a) withdraw or revoke the authorisation of a performance study;**
- (b) suspend, temporary halt or terminate a performance study;**
- (c) require the sponsor to modify any aspect of a performance study.**

**0b. Before the Member State concerned takes any of the measures referred to in paragraph 0a it shall, except where immediate action is required, ask the sponsor and/or the investigator for their opinion. That opinion shall be delivered within seven days.**

1. Where a Member State has **taken a measure referred to in paragraph 0a or has** refused, suspended or terminated a clinical performance study, ~~or has called for a substantial modification or temporary halt of a clinical performance study,~~ or has been notified by the sponsor of the early termination of a clinical performance study on safety grounds, that Member State shall communicate its **this** decision and the grounds therefor to all Member States and the Commission by means of the electronic system referred to in Article 51.
2. Where an application is withdrawn by the sponsor prior to a decision by a Member State that ~~Member State shall inform~~ **information shall be available to** all the other Member States and the Commission ~~of that fact,~~ by means of the electronic system referred to in Article 51.

Article 55

*Information by the sponsor in the event of temporary halt or termination of interventional clinical performance studies or of other ~~clinical~~ performance studies involving risks for the subjects of the studies*

1. If the sponsor has temporarily halted a ~~clinical~~ performance study ~~on safety grounds~~ **or has early terminated a performance study**, he shall inform the Member States concerned within 15 days of the temporary halt **or early termination, providing a justification. In case the sponsor has temporarily halted or early terminated the performance study on safety grounds, he shall inform the Member states concerned thereof within 24 hours.**
  
2. The sponsor shall notify each Member State concerned of the end of a ~~clinical~~ performance study in relation to that Member State, ~~providing a justification in the event of early termination.~~ That notification shall be made within 15 days from the end of the ~~clinical~~ performance study in relation to that Member State.
  - 2a. If the study is conducted in more than one Member State, the sponsor shall notify all Member States concerned of the overall end of the ~~clinical~~ performance study. That notification shall be made within 15 days from the overall end of the ~~clinical~~ performance study.
  
3. Within one year from the end of the ~~clinical~~ performance study **or within three months from the early termination**, the sponsor shall submit to the Member States concerned **through the electronic system referred to in Article 51** ~~a summary of the results of the clinical performance study in form of a clinical performance study report referred to in Section 2.3.3. of Part A of Annex XII. Where, for scientific reasons, it is not possible to submit the clinical performance study report within one year~~ **after the completion of the study**, it shall be submitted as soon as it is available. In this case, the clinical performance study ~~protocol~~ **plan** referred to in Section 2.3.2. of Part A of Annex XII shall specify when the results of the ~~clinical~~ performance study are going to be submitted, together with an explanation.

4. *A summary of the performance study report shall be provided by the sponsor at least within 1 year following the provision of the performance study report according to paragraph 3. the summary of the performance study report shall be written in a way that is readily understood by the intended user of the device.*
  
5. *Submission of information and reports according to paragraphs 1 to 4 shall be accomplished through the electronic system referred to in Article 51. The reports according to paragraphs 3 and 4 shall become publicly accessible through the electronic system, at the latest when the device is CE-marked and before it is placed on the market.*

#### *Article 56*

*Interventional clinical performance studies and other ~~clinical~~ performance studies involving risks for the subjects of the studies conducted in more than one Member State*

1. By means of the electronic system referred to in Article 51, the sponsor of the ~~clinical~~ performance study to be conducted in more than one Member State may submit, for the purpose of Article 49, a single application that, upon receipt, is transmitted electronically to the Member States concerned *who have voluntarily agreed to that procedure concerning that performance study.*
  
2. In the single application, the sponsor shall propose one of the Member States concerned as coordinating Member State. ~~If that Member State does not wish to be the coordinating Member State, it~~ *Concerned Member States shall agree, within six days of submission of the single application, agree on one of them taking the role of* ~~with another Member State concerned that the latter shall be the coordinating Member State. If no other Member State accepts to be the~~ *they do not agree on a* coordinating Member State, the Member State *one* proposed by the sponsor shall ~~be the coordinating Member State~~ *take that role.* ~~If another Member State than the one proposed by the sponsor becomes coordinating Member State, the~~ *The* deadlines referred to in Article 49(2) shall start on the day following the *notification of the coordinating Member State to the sponsor (notification date)* ~~acceptance.~~

3. Under the direction of the coordinating Member State referred to in paragraph 2, the Member States concerned shall coordinate their assessment of the application, in particular of the documentation submitted in accordance with Chapter I of Annex XIII, except for Sections **1.11a.**, 4.2, 4.3 and 4.4 **and Section 2.3.2.(c) of Part A of Annex XII** thereof which shall be assessed separately by each Member State concerned.

The coordinating Member State shall:

- (aa) within 6 days of receipt of the single application notify the sponsor that it is the coordinating Member State (notification date);**
- (a) within ~~6~~ **10** days of receipt of the single application notify the sponsor whether the ~~clinical~~ performance study falls within the scope of this Regulation and whether the application is complete, except for the documentation submitted in accordance with Sections **1.11a.**, 4.2, 4.3 and 4.4 of Chapter I of Annex XIII **and Section 2.3.2.(c) of Part A of Annex XII** for which each Member State shall verify the completeness. Article 49(2) to (4) shall apply to the coordinating Member State in relation to the verification that the ~~clinical~~ performance study falls within the scope of this Regulation and that the application is complete, **having taken into account considerations expressed by the other Member States concerned**, except for the documentation submitted in accordance with Sections **1.11a.**, 4.2, 4.3 and 4.4 of Chapter I of Annex XIII **and Section 2.3.2.(c) of Part A of Annex XII**. **Concerned Member States may communicate to the coordinating Member State any considerations relevant to the validation of the application within seven days from the notification date.** Article 49(2) to (4) shall apply to each Member State in relation to the verification that the documentation submitted in accordance with Sections **1.11a.**, 4.2, 4.3 and 4.4 of Chapter I of Annex XIII **and Section 2.3.2.(c) of Part A of Annex XII** is complete;
- ~~(b) establish the results of the coordinated assessment in a report to be taken into account by the other Member States concerned when deciding on the sponsor's application in accordance with Article 49(5).~~

*(c) establish the results of its assessment in a draft assessment report to be transmitted within 26 days after the validation date to the concerned Member States. Until day 38 after the validation date the other concerned Member States shall transmit their comments and proposals on the draft assessment report and the underlying application to the coordinating Member State, which shall take due account of it in the finalization of the final assessment report, to be transmitted within 45 days following the validation date to the sponsor and the concerned Member States. The final assessment report shall be taken into account by the other Member States concerned when deciding on the sponsor's application in accordance with Article 49 (5), except for Sections 1.11a., 4.2, 4.3 and 4.4 of Chapter I of Annex XIII and Section 2.3.2.(c) of Part A of Annex XII, which shall be assessed separately by each Member State concerned.*

*As concerns the assessment of the documentation related to Sections 1.11a., 4.2, 4.3 and 4.4 of Chapter I of Annex XIII and Section 2.3.2.(c) of Part A of Annex XII, done separately by each Member State, the Member State may request, on a single occasion, additional information from the sponsor. The expiry of the deadline pursuant paragraph 2 shall be suspended from the date of the request until such time as the additional information has been received.*

*3a. The coordinating Member State may also extend the periods referred to in paragraph 3 by a further 50 days, for the purpose of consulting with experts. In such case, the periods referred to in paragraphs 3 of this Article shall apply mutatis mutandis.*

- 3aa. *The Commission may, by means of implementing acts, set out the procedures and timescales for a coordinated assessment led by the coordinating Member State, that shall be taken into account by concerned Member States when deciding on the sponsor's application notification. Such implementing acts may also cover the procedures for coordinated assessment in the case of substantial modifications pursuant to paragraph 4 and in the case of reporting of events pursuant to Article 57(4) or in the case of clinical investigations of combination products between medical devices and medicinal products, where the latter are under a concurrent coordinated assessment of a clinical trial under Regulation (EU) 536/2014. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).***
- 3b. *Where the conclusion of the coordinating Member State is that the conduct of the performance study is acceptable or acceptable subject to compliance with specific conditions, that conclusion shall be deemed to be the conclusion of the Member State(s) concerned.***

***Notwithstanding the previous subparagraph, a Member State concerned may disagree with the conclusion of the coordinating Member State concerning the area of joint assessment only on the following grounds:***

- (a) when it considers that participation in the performance study would lead to a subject receiving an inferior treatment than in normal clinical practice in the Member State concerned;***
- (b) infringement of national law;***
- (c) considerations as regards subject safety and data reliability and robustness submitted under paragraph 3 point (b).***

***Where a Member State concerned disagrees with the conclusion, it shall communicate its disagreement, together with a detailed justification, through the electronic system referred to in Article 51 to the Commission, to all Member States concerned, and to the sponsor.***



- 3c. *A Member State concerned shall refuse to authorise a performance study if it disagrees with the conclusion of the coordinating Member State as regards any of the grounds referred to in the second subparagraph of paragraph 3b, or if it finds, on duly justified grounds, that the aspects addressed in Sections 1.11a., 4.2, 4.3 and 4.4 of Chapter I of Annex XIII are not complied with, or where an Ethics committee has issued a negative opinion which in accordance with the law of the Member State concerned is valid for that entire Member State. That Member State shall provide for an appeal procedure in respect of such refusal.*
- 3ca. *Each Member State concerned shall notify the sponsor through the electronic system referred to in Article 51 as to whether the performance study is authorised, whether it is authorised subject to conditions, or whether authorisation is refused. Notification shall be done by way of one single decision within five days from the reporting date. An authorisation of a performance study subject to conditions is restricted to conditions which by their nature cannot be fulfilled at the time of that authorisation.*
- 3d. *Where the conclusion of the coordinating Member State report is that the clinical performance study is not acceptable, that conclusion shall be deemed to be the conclusion of all Member States concerned.*
4. The substantial modifications *as* referred to in Article 53 shall be notified to the Member States concerned by means of the electronic system referred to in Article 51. Any assessment as to whether there are grounds for refusal as referred to in ~~Article 53~~ **paragraph 3b** shall be carried out under the direction of the coordinating Member State, **except for substantial modifications concerning sections 1.11a., 4.2, 4.3 and 4.4 of Chapter I of Annex XIII and Section 2.3.2.(c) of Part A of Annex XII, which shall be assessed by each concerned Member State on its own.**
5. For the purpose of Article 55(3), the sponsor shall submit the ~~clinical~~ performance study report to the Member States concerned by means of the electronic system referred to in Article 51.

6. The Commission shall provide ~~secretarial~~ **administrative** support to the coordinating Member State in the accomplishment of its tasks provided for in this Chapter.

#### *Article 56a*

##### *Review of performance studies rules*

*Five years after the date referred to in the first paragraph of Article 90, the Commission shall make a report on the application of Article 58 of the present Regulation and propose a review of the provision of Article 56 in order to ensure a coordinated assessment procedure of performance study conducted in more than one Member State.*

#### *Article 57*

*Recording and reporting of events occurring during interventional clinical performance studies and other ~~clinical~~ performance studies involving risks for the subjects of the studies*

1. The sponsor shall fully record any of the following:
  - (a) an adverse event identified in the ~~clinical~~ performance study ~~protocol~~ as critical to the evaluation of the results of the ~~clinical~~ performance study **according to the clinical performance study plan** ~~in view of the purposes referred to in Article 48(1)~~;
  - (b) a serious adverse event;
  - (c) a device deficiency that might have led to a serious adverse event if suitable action had not been taken, intervention had not occurred, or circumstances had been less fortunate;
  - (d) new findings in relation to any event referred to in points (a) to (c).

2. The sponsor *by means of the electronic system referred to in Article 51* shall report to all Member States where a ~~clinical~~ performance study is conducted without delay any of the following:
  - (a) a serious adverse event that has a causal relationship with the device ~~for performance evaluation~~, the comparator or the study procedure or where such causal relationship is reasonably possible;
  - (b) a device deficiency that might have led to a serious adverse event if suitable action had not been taken, intervention had not occurred, or circumstances had been less fortunate;
  - (c) new findings in relation to any event referred to in points (a) to (b).

The time period for reporting shall take account of the severity of the event. Where necessary to ensure timely reporting, the sponsor may submit an initial incomplete report followed up by a complete report.

3. The sponsor shall also report to the Member States concerned any event referred to in paragraph 2 occurring in third countries in which a ~~clinical~~ performance study is performed under the same ~~clinical~~ performance study ~~protocol~~ *plan* as the one applying to a ~~clinical~~ performance study covered by this Regulation *by means of the electronic system referred to in Article 51*.
4. In the case of a ~~clinical~~ performance study for which the sponsor has used the single application referred to in Article 56, the sponsor shall report any event as referred to in paragraph 2 by means of the electronic system referred to in Article 51. Upon receipt, this report shall be transmitted electronically to all Member States concerned.

Under the direction of the coordinating Member State referred to in Article 56(2), the Member States shall coordinate their assessment of serious adverse events and device deficiencies to determine whether a ~~clinical~~ performance study needs to be terminated, suspended, temporarily halted or modified.

This paragraph shall not affect the rights of the other Member States to perform their own evaluation and to adopt measures in accordance with this Regulation in order to ensure the protection of public health and patient safety. The coordinating Member State and the Commission shall be kept informed of the outcome of any such evaluation and the adoption of any such measures.

5. In the case of post-market performance follow-up studies referred to in Article 52(1), the provisions on vigilance contained in Articles 59 to 64 shall apply instead of this Article.
6. ***Notwithstanding paragraph 5, this Article shall however apply where a causal relationship between the serious adverse event and the preceding investigational procedure has been established.***

#### *Article 58*

##### *Implementing acts*

The Commission may, by means of implementing acts, adopt the modalities and procedural aspects necessary for the implementation of this Chapter, as regards the following:

- (a) harmonised ***electronic*** forms for the application for ~~clinical~~ performance studies and their assessment as referred to in Articles 49 and 56, taking into account specific categories or groups of devices;
- (b) the functioning of the electronic system referred to in Article 51;
- (c) harmonised ***electronic*** forms for the notification of post-market ***performance*** follow-up ~~performance~~ studies as referred to in Article 52(1), and of substantial modifications as referred to in Article 53;
- (d) the exchange of information between Member States as referred to in Article 54;
- (e) harmonised ***electronic*** forms for the reporting of serious adverse events and device deficiencies as referred to in Article 57;
- (f) the timelines for the reporting of serious adverse events and device deficiencies, taking into account the severity of the event to be reported as referred to in Article 57;

- (g) uniform application of the requirements regarding the clinical evidence/data needed to demonstrate compliance with the general safety and performance requirements specified in Annex I.*

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

## Chapter VII

### *Post-market surveillance, vigilance and market surveillance*

#### **SECTION 0 – POST-MARKET SURVEILLANCE**

##### *Article 58a*

###### *Post-market surveillance system of the manufacturer*

- ~~1. *The manufacturer shall ensure compliance with the provisions of this Regulation throughout the entire lifetime of the devices he has made available on the market or put into service.*~~
2. *For any device, proportionate to the risk class and appropriate for the type of device, manufacturers shall plan, establish, document, implement, maintain and update a post-market surveillance system which shall be an integral part of the manufacturer's quality management system according to Article 8(6).*
3. *The post-market surveillance system shall be suitable to actively and systematically gather, record and analyse relevant data on the quality, performance and safety of a device throughout its entire lifetime, to draw the necessary conclusions and to determine, implement and monitor any preventive and corrective actions.*
4. *Data gathered by the manufacturer's post-market surveillance system shall in particular be used:*
  - (a) *to update the benefit risk determination and risk management, the design and manufacturing information, the instructions for use and the labelling;*
  - (b) *to update the performance evaluation;*
  - (c) *to update the summary of safety and performance as referred to in Article 24;*

- (d) for the identification of needs for preventive, corrective or field safety corrective action;*
- (e) for the identification of possibilities to improve the usability, performance and safety of the device;*
- (f) when relevant, to contribute to the post-market surveillance of other devices;*
- (g) to detect and report trends in accordance with Article 59a.*

*The technical documentation shall be updated accordingly.*

- 6. If in the course of the post-market surveillance a need for preventive and corrective action is identified, the manufacturer shall implement the appropriate measures and, where applicable, inform the notified body and the competent authorities concerned. When a serious incident is identified or a field safety corrective action is implemented, this shall be reported in accordance with Article 59.*

#### *Article 58b*

##### *Post-market surveillance plan*

*The post-market surveillance system as referred to in Article 58a shall be based on a post-market surveillance plan, the requirements of which are set out in Section 1.1 of Annex IIa. The post-market surveillance plan shall be part of the technical documentation as specified in Annex II.*

#### *Article 58c*

##### *Periodic safety update report*

- 1. Per device and where relevant per category or group of devices, the manufacturer shall prepare a periodic safety update report summarising the results and conclusions of the analyses of the gathered post-market surveillance data according to Annex IIa together with a rationale and description of any preventive and corrective actions taken.*

*Throughout the lifetime of the device concerned this report shall set out:*

- (a) the conclusion of the benefit risk determination;*

- (b) the main findings of the Post Market Performance Follow-up Report and*
- (c) the volume of sales of devices and an estimate of the population that use the device involved and, where practicable, the usage frequency of the device.*

*The report shall be updated at least annually; and be part of the technical documentation as specified in Annex II.*

- 2. Manufacturers of devices in class C and D shall submit reports by means of the electronic system referred to in Article 64a to the notified body involved in the conformity assessment in accordance with Article 40. The notified body shall review the report and add its evaluation to the database with details of any action taken. Such reports and the notified body evaluation shall be available to competent authorities through the electronic system.*
- 3. Manufacturers of devices other than those referred to in paragraph 2, shall make reports available to the notified body involved in the assessment and to competent authorities on request.*



## SECTION 1 – VIGILANCE

### *Article 59*

#### *Reporting of serious incidents and field safety corrective actions*

1. Manufacturers of devices, ***made available on the Union market***, other than devices for performance evaluation, shall report, through the electronic system referred to in Article 60 ~~60~~ ***64a***, the following:
  - (a) any serious incident ***involving*** ~~in respect of~~ devices made available on the Union market, ***except expected erroneous results which are clearly documented and quantified in the product information and in the technical documentation and are subject to trend reporting pursuant to Article 59a***;
  - (b) any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market, if the reason for the field safety corrective action is not limited to the device made available in the third country.
- 1a. As a general rule, the time period for reporting shall take account of the severity of the serious incident.***
- 1b. Manufacturers shall make the report any serious incident as referred to in point (a) the first subparagraph without delay, and no later than 15 days after they have become aware of the event and immediately after the manufacturer has established the causal relationship with their device or that such causal relationship is reasonably possible, and not later than 15 days after they have become aware of the event.***

~~The time period for reporting shall take account of the severity of the incident.~~

- 1c. Notwithstanding paragraph 1b, in case of a serious public health threat the report shall be provided immediately, and not later than 2 days after awareness by the manufacturer of this threat.**
- 1d. Notwithstanding paragraph 1b, in case of death or unanticipated serious deterioration in state of health the report shall be provided immediately after the manufacturer established or suspected a causal relationship between the device and the event but not later than 10 elapsed days following the date of awareness of the event.**
- 1e.** Where necessary to ensure timely reporting, the manufacturer may submit an initial incomplete report followed up by a complete report.
- 1f. If after becoming aware of a potentially reportable incident there is still uncertainty about whether the event is reportable, the manufacturer shall submit a report within the timeframe required for that type of incident.**
- 1g. Except in cases of urgency where the manufacturer need to undertake the field safety corrective action immediately, without undue delay, the manufacturer shall report the field safety corrective action referred to in paragraph 1, point (b) in advance of the field safety corrective action being undertaken.**
- 2.** For similar serious incidents occurring with the same device or device type and for which the root cause has been identified or the field safety corrective action implemented **or where the incidents are common and well documented, the** manufacturers may provide periodic summary reports instead of individual **serious** incident reports, on condition that the **coordinating competent authority referred to in Article 61(6), in consultation with the** competent authorities referred to in points (a), ~~(b)~~ and ~~(e)~~ of Article ~~64a~~ ~~60(5)~~7), ~~has~~ have agreed with the manufacturer on the format, content and frequency of the periodic summary reporting. **Where a single competent authority is referred to in points (a), and (-b) of Article 64a(7), the manufacturer may provide periodic summary reports on agreement with that competent authority.**

3. The Member States shall take ~~all~~ appropriate measures to encourage healthcare professionals, users and patients to report to their competent authorities, suspected serious incidents referred to in point (a) of paragraph 1. They shall record ~~such~~ reports ***that they receive*** centrally at national level. Where a competent authority of a Member State obtains such reports, it shall take the necessary steps to ensure that the manufacturer of the device concerned is informed of the ***suspected serious*** incident.

***The manufacturer of the device concerned shall provide to the competent authority of the Member State where the event occurred a report on the serious incident in accordance with paragraph 1 and ensure the appropriate follow-up. If the manufacturer considers that the event is not a serious incident or an increase in expected erroneous results which will be covered by trend reporting according to Article 59(1a), it shall provide an explanatory statement*** ~~The manufacturer shall ensure the appropriate follow-up.~~

~~The Member States shall coordinate between them the development of standard web-based structured forms for reporting of serious incidents by healthcare professionals, users and patients.~~

***If the competent authority does not agree with the conclusion of the explanatory statement, it may require the manufacturer to provide a report in accordance with this Article and to take or require the manufacturer to take the appropriate corrective action.***

4. ~~Health institutions manufacturing and using devices referred to in Article 4(4) shall report any serious incidents and field safety corrective actions referred to in paragraph 1 to the competent authority of the Member State in which the health institution is located.~~

*Article 62 59a*

*Trend reporting*

- 1. Manufacturers of devices classified in class C and D shall report to **by means of** the electronic system referred to in Article ~~60~~ **64a** any statistically significant increase in the frequency or severity of incidents that are not serious incidents or of expected undesirable effects that **could** have a significant impact on the risk-benefit analysis referred to in Sections *I.1* and *I.5* of Annex I and which have led or may lead to unacceptable risks to the health or safety of patients, users or other persons when weighted against the intended benefits **or of any significant increase in expected erroneous results**. The significant increase shall be established in comparison to the **stated performance of the device according to Annex I Section II.6.1 (a) and (b) and** foreseeable frequency or severity of such incidents or expected undesirable effects in respect of the device, or category or group of devices, in question during a specific time period **specified in the technical documentation and product information** as established in the manufacturer's conformity assessment. **The manufacturer shall define how to manage these events and the methodology used for determining any statistically significant increase in the frequency or severity of this these events or change in performance, as well as the observation period, in the post-market surveillance plan pursuant to Article 58b.** Article ~~61~~ shall apply.*
- 1a. The competent authorities may conduct their own assessments on the trend reports referred to in paragraph 1 and require the manufacturer to adopt appropriate measures in accordance with the present regulation in order to ensure the protection of public health and patient safety. The competent authority shall inform the Commission, the other competent authorities and the notified body that issued the certificate, of the results of such evaluation and of the adoption of such measures.*

*Article 60*

*Electronic system on vigilance*

1. ~~The Commission shall, in collaboration with the Member States, set up and manage an electronic system to collate and process the following information:~~
  - (a) ~~the reports by manufacturers on serious incidents and field safety corrective actions referred to in Article 59(1);~~
  - (b) ~~the periodic summary reports by manufacturers referred to in Article 59(2);~~
  - (c) ~~the reports by competent authorities on serious incidents referred to in the second subparagraph of Article 61(1);~~
  - (d) ~~the reports by manufacturers on trends referred to in Article 62;~~
  - (e) ~~the field safety notices by manufacturers referred to in Article 61(4);~~
  - (f) ~~the information to be exchanged between the competent authorities of the Member States and between them and the Commission in accordance with Article 61(3) and (6).~~
  
2. ~~The information collated and processed by the electronic system shall be accessible to the competent authorities of the Member States, to the Commission and to the notified bodies.~~
  
3. ~~The Commission shall ensure that healthcare professionals and the public have appropriate levels of access to the electronic system.~~
  
4. ~~On the basis of arrangements between the Commission and competent authorities of third countries or international organisations, the Commission may grant those competent authorities or international organisations access to the database at the appropriate level. Those arrangements shall be based on reciprocity and make provision for confidentiality and data protection equivalent to those applicable in the Union.~~

5. ~~The reports on serious incidents and field safety corrective actions referred to in points (a) and (b) of Article 59(1), the periodic summary reports referred to in Article 59(2), the reports on serious incidents referred to in the second subparagraph of Article 61(1) and the trend reports referred to in Article 62 shall be automatically transmitted upon receipt via the electronic system to the competent authorities of the following Member States:~~
- ~~(a) the Member State where the incident occurred;~~
  - ~~(b) the Member State where the field safety corrective action is being or is to be undertaken;~~
  - ~~(c) the Member State where the manufacturer has his registered place of business;~~
  - ~~(d) where applicable, the Member State where the notified body, that issued a certificate in accordance with Article 4 3 for the device in question, is established.~~

#### *Article 61*

##### *Analysis of serious incidents and field safety corrective actions*

- 0. *Following the reporting of a serious incident pursuant to Article 59(1), the manufacturer shall without delay perform the necessary investigations of the serious incident and the concerned devices. This shall include risk assessment of the incident and field safety corrective action taking into account criteria outlined in paragraph 2. The manufacturer shall co-operate with the competent authorities and where relevant with the concerned notified body during these investigations and shall not perform any investigation which involves altering the device or a sample of the batch concerned in a way which may affect any subsequent evaluation of the causes of the incident prior to informing the competent authorities of such action.***

1. Member States shall take the necessary steps to ensure that any information regarding a serious incident that has occurred within their territory or a field safety corrective action that has been or is to be undertaken within their territory, and that is brought to their knowledge in accordance with Article 59 is, at national level, evaluated centrally by their competent authority, if possible together with the manufacturer, **and, where relevant, with the notified body concerned.**

~~If in the case of reports received in accordance with Article 59 (3) the competent authority ascertains that the reports relate to a serious incident it shall notify without delay those reports to the electronic system referred to in Article 60, unless the same incident has already been reported by the manufacturer.~~

2. ~~The~~ **In the context of the evaluation referred to in paragraph 0, the** national competent authorities **authority** shall **assess the risks arising from** ~~carry out a risk assessment with regard to~~ **the** reported serious incidents **and** ~~or~~ field safety corrective actions, taking into account the **protection of public health and the** criteria such as causality, detectability and probability of recurrence of the problem, frequency of use of the device, probability of occurrence of **direct or indirect** harm and severity of **that** harm, clinical benefit of the device, intended and potential users, and population affected. ~~They~~ **It** shall also evaluate the adequacy of the field safety corrective action envisaged or undertaken by the manufacturer and the need for and kind of any other corrective action, **in particular taking into account the principle of inherent safety laid down in Annex I.**

**Upon request by the national competent authority, the manufacturer shall provide for all documents necessary for the risk assessment.**

- 2a. ~~They~~ **The national competent authorities** shall monitor the manufacturer's investigation of ~~the~~ **a serious** incident. **Where necessary, a competent authority may intervene in a manufacturer's investigation or initiate an independent investigation.**

- 2b. *The manufacturer shall provide a final report setting out its findings by means of the electronic system referred to in Article 64a. The report shall set out conclusions and where relevant indicate corrective actions to be taken.*
3. *In the case of companion diagnostic, the evaluating competent authority or the coordinating competent authority referred to in paragraph 6 shall inform the relevant competent authority for medicinal products, or the European Medicines Agency (EMA), that was consulted by the notified body in accordance with the procedures set out in Section 6.2 of Annex VIII and Section 3.6 of Annex IX.*
4. After carrying out the ~~assessment~~ *evaluation*, the evaluating competent authority shall, through the electronic system referred to in Article ~~64a~~ *60*, inform without delay the other competent authorities of the corrective action taken or envisaged by the manufacturer or imposed on him to minimise the risk of recurrence of a serious incident, including information on the underlying events and the outcome of its assessment.
5. The manufacturer shall ensure that ~~the users of the device in question are informed without delay of~~ *information about the field safety* corrective action taken *is brought without delay to the attention of users of the device in question* by means of a field safety notice. *The field safety notice shall be edited in an official Union language or languages determined by the Member State where the field safety corrective action is taken.* Except in case of urgency, the content of the draft field safety notice shall be submitted to the evaluating competent authority or, in cases referred to in paragraph ~~65~~ of this Article, the coordinating competent authority to allow them to make comments. Unless duly justified by the situation of the individual Member State, the content of the field safety notice shall be consistent in all Member States.



*The field safety notice shall allow the correct identification of the device or devices involved, including the UDI, and of the manufacturer, including the SRN, that has undertaken the field safety corrective action. The field safety notice shall explain, in a clear manner, without playing down the level of risk, the reasons for field safety corrective action with reference to the device deficiency or malfunction and associated risks for patient, user or other person and shall clearly indicate all the actions to be taken by users.*

The manufacturer shall enter the field safety notice in the electronic system referred to in Article ~~60~~ **64a** through which that notice shall be accessible to the public.

6. The competent authorities shall ~~designate~~ **nominate** a coordinating competent authority to coordinate their assessments referred to in paragraph 2 in the following cases:
  - (a) where **there is concern regarding a particular similar serious incident or cluster of serious** incidents related to the same device or type of device of the same manufacturer ~~occur~~ in more than one Member State;
  - (b) where the **appropriateness of a** field safety corrective action **that is proposed by a manufacturer is being or is to be undertaken** in more than one Member State **is in question**.

Unless otherwise agreed between the competent authorities, the coordinating competent authority shall be ~~the one of~~ the Member State where the manufacturer **or the authorised representative** has his registered place of business.

***The competent authorities shall actively participate in a coordination procedure. This procedure shall include the following:***

- ***designation of a coordinating authority on a case by case basis, when required;***
- ***a definition of the coordinated assessment process;***
- ***tasks and responsibilities of the coordinating authority and the involvement of other competent authorities.***

The coordinating competent authority shall, ~~inform~~ **through the electronic system referred to in Article 64a, inform** the manufacturer, the other competent authorities and the Commission that it has assumed the role of coordinating authority.

7. ~~The coordinating competent authority shall carry out the following tasks:~~
- ~~(a) to monitor the investigation of the serious incident by the manufacturer and the corrective action to be taken;~~
  - ~~(b) to consult with the notified body that issued a certificate in accordance with Article 43 for the device in question regarding the impact of the serious incident on the certificate;~~
  - ~~(c) to agree with the manufacturer and the other competent authorities referred to in points (a) to (c) of Article 60 (5) on the format, content and frequency of periodic summary reports in accordance with Article 59(2);~~
  - ~~(d) to agree with the manufacturer and other competent authorities concerned on the implementation of the appropriate field safety corrective action;~~
  - ~~(e) to inform the other competent authorities and the Commission, through the electronic system referred to in Article 60, of the progress in and the outcome of its assessment.~~
- The designation of a coordinating competent authority shall not affect the rights of the other competent authorities to perform their own assessment and to adopt measures in accordance with this Regulation in order to ensure the protection of public health and patient safety. The coordinating competent authority and the Commission shall be kept informed of the outcome of any such assessment and the adoption of any such measures.
8. The Commission shall provide ~~secretarial~~ **administrative** support to the coordinating competent authority in the accomplishment of its tasks under this Chapter.

*Article 62*  
*Trend reporting*

~~Manufacturers of devices classified in class C or D shall report to the electronic system referred to in Article 60 any statistically significant increase in the frequency or severity of incidents that are not serious incidents or of expected undesirable *side* effects that have a significant impact on the risk-benefit analysis referred to in Sections 1 and 5 of Annex I and which have led or may lead to unacceptable risks to the health or safety of patients, users or other persons when weighted against the intended benefits. The significant increase shall be established in comparison to the foreseeable frequency or severity of such incidents or expected undesirable *side* effects in respect of the device, or category or group of devices, in question during a specific time period as established in the manufacturer's conformity assessment. Article 61 shall apply.~~

*Article 63*  
*Documentation of vigilance data*

~~Manufacturers shall update their technical documentation with information on incidents received from, healthcare professionals, patients and users, serious incidents, field safety corrective actions, periodic summary reports referred to in Article 59, trend reports referred to in Article 62 and field safety notices referred to in Article 61(4). They shall make this documentation available to their notified bodies, which shall assess the impact of the vigilance data on the conformity assessment and the certificate issued.~~

*Article 63a*  
*Analysis of vigilance data*

***The Commission shall, in collaboration with the Member States, put in place systems and processes to proactively monitor the data available in the database referred to in Article 64a, in order to identify trends, patterns or signals in the data that may identify new risks or safety concerns.***

***When a previously unknown risk is identified or the frequency of an anticipated risk significantly and adversely changes the risk-benefit determination, the competent authority or, where appropriate, the coordinating competent authority shall inform the manufacturer, or where applicable the authorised representative, who shall take the necessary corrective actions.***

## Article 64

### Implementing acts

The Commission may, by means of implementing acts, **and after consultation of the MDCG**, adopt the modalities and procedural aspects necessary for the implementation of Articles ~~59-61~~ to 63a **and 64a** as regards the following:

- (a) typology of serious incidents and field safety corrective actions in relation to specific devices, or categories or groups of devices;
- (b) ~~harmonised forms for~~ the reporting of serious incidents and field safety corrective actions, **field safety notices**, periodic summary reports, **periodic safety update reports** and trend reports by manufacturers as referred to in Articles 58c, 59, 59a and ~~61~~ ~~62~~;
- (ba) standard web-based structured forms including a minimum data set for electronic reporting of serious incidents by healthcare professionals, users and patients;**
- (c) timelines for the reporting of ~~serious incidents and~~ field safety corrective actions, periodic summary reports, ~~and~~ trend reports **and periodic safety update reports** by manufacturers, taking into account the severity of the event to be reported as referred to in Articles 59 and 58c ~~62~~;
- (d) harmonised forms for the exchange of information between competent authorities as referred to in Article 61.
- (e) procedures for designation of a coordinating competent authority, the coordinated assessment process, tasks and responsibilities of the coordinating competent authority and involvement of other competent authorities in this process.**

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

*Article 60 64a*

*Electronic system on vigilance*

1. The Commission shall, in collaboration with the Member States, ~~set up and manage an electronic system to~~ collate and process the following information ***by means of the electronic system set up pursuant to Article 25 including a link to the product information in accordance with Article 22a.***
  - (a) the reports by manufacturers on serious incidents and field safety corrective actions referred to in Article 59(1) ***and Article 61(1)***;
  - (b) the periodic summary reports by manufacturers referred to in Article 59(2);
  - (c) ~~the reports by competent authorities on serious incidents referred to in the second subparagraph of Article 61(1)~~;
  - (d) the reports by manufacturers on trends referred to in Article ~~62~~***59a***;
  - (da) the periodic safety update reports referred to in Article 58c;***
  - (e) the field safety notices by manufacturers referred to in Article 61(~~54~~);
  - (f) the information to be exchanged between the competent authorities of the Member States and between them and the Commission in accordance with Article 61(~~43~~) and (~~76~~).
2. The information collated and processed by the electronic system shall be accessible to the competent authorities of the Member States, to the Commission and to the notified bodies ***that issued a certificate for the device in question in accordance with Article 41.***
3. The Commission shall ensure that healthcare professionals and the public have appropriate levels of access to the electronic system.
4. On the basis of arrangements between the Commission and competent authorities of third countries or international organisations, the Commission may grant those competent authorities or international organisations access to the database at the appropriate level. Those arrangements shall be based on reciprocity and make provision for confidentiality and data protection equivalent to those applicable in the Union.

5. The reports on serious incidents ~~and field safety corrective actions~~ referred to in points (a) ~~and (b)~~ of Article 59(1), ~~the periodic summary reports referred to in Article 59(2),~~ **and** the reports on serious incidents referred to in the second subparagraph of Article 61(1) ~~and the trend reports referred to in Article 62~~ shall be automatically transmitted, upon receipt, via the electronic system, to the competent ~~authorities~~ **authority** of the following Member States:
- (a) ~~the Member State~~ where the incident occurred;
- 5a. *Trend reports on expected erroneous results leading to serious incidents referred to in points (a) of Article 59(1) shall be automatically transmitted upon receipt via the electronic system to the competent authorities of the Member State where the incidents occurred;***
6. ***The reports on field safety corrective actions referred to in point (b) of Article 59(1) shall be automatically transmitted upon receipt via the electronic system to the competent authority of the following Member States:***
- (~~ba~~) the Member State where the field safety corrective action is being or is to be undertaken;
  - (~~eb~~) the Member State where the manufacturer ***or his authorised representative*** has his registered place of business;
  - (~~d~~) ~~where applicable, the Member State where the notified body, that issued a certificate in accordance with Article 43 for the device in question, is established.~~
7. ***The periodic summary reports referred to in Article 59(2) shall be automatically transmitted upon receipt via the electronic system to the competent authority of the following Member States:***
- (a) ***the Member State that agreed on the periodic summary report;***
  - (b) ***the Member State where the manufacturer or his authorised representative has his registered place of business.***
8. ***The information referred to in paragraphs 5 to 7 shall be automatically transmitted, upon receipt, through the electronic system, to the notified body that issued the certificate for the device in question in accordance with Article 43.***

## SECTION 2 – MARKET SURVEILLANCE

### Article 65

#### Market surveillance activities

1. The competent authorities shall perform appropriate checks on the **conformity** characteristics and performance of devices including, where appropriate, review of documentation and physical or laboratory checks on the basis of adequate samples. They shall, **in particular**, take account of established principles regarding risk assessment and risk management, vigilance data and complaints.
  - 1a. **The competent authorities shall draw up annual surveillance activities plans and allocate a sufficient number of competent human and material resources needed to carry out those activities taking into account the European market surveillance program developed by the MDCG according to Article 77 and local circumstances.**
  - 1b. ~~The~~ **For the purpose referred to in the paragraph 1, the** competent authorities ~~may~~:
    - (a) **may, inter alia** require economic operators to make available the documentation and information necessary for the purpose of carrying out their activities and, where necessary and justified, ~~enter the premises of economic operators and take~~ **provide** the necessary samples of devices **free of charge**;
    - (b) **and shall carry out both announced and, if necessary for control purposes, unannounced inspections of the premises of economic operators, as well as suppliers and/or subcontractors, and, where necessary, at the facilities of professional users.**
  - 1c. **The competent authorities shall prepare annual summary of the results of the surveillance activities and make it accessible to other competent authorities by means of the electronic system referred to in Article 73b.**
  - 1d. **The competent authorities** ~~They may~~ **confiscate**, destroy or otherwise render inoperable devices presenting a serious risk **or falsified products** where they deem it necessary **in the interest of the protection of public health.**

2. The Member States shall ~~periodically~~ review and assess the functioning of their surveillance activities. Such reviews and assessments shall be carried out at least every four years and the results thereof shall be communicated to the other Member States and the Commission. The Member State concerned shall make a summary of the results accessible to the public **by means of the electronic system referred to in Article 73b**.
3. The competent authorities of the Member States shall coordinate their market surveillance activities, cooperate with each other and share with each other and with the Commission the results thereof, **to provide for a harmonized high level of market surveillance in all Member States**.

Where appropriate, the competent authorities of the Member States shall agree on work-sharing, **joint market surveillance activities** and specialisation.

4. Where more than one authority in a Member State is responsible for market surveillance and external border controls, those authorities shall cooperate with each other, by sharing information relevant to their role and functions.
5. **Where appropriate,** ~~t~~The competent authorities of the Member States shall cooperate with the competent authorities of third countries with a view to exchanging information and technical support and promoting activities relating to market surveillance.

#### *Article 66*

##### *Electronic system on market surveillance*

- ~~1-~~ The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process the following information:
  - (a) ~~information in relation to non-compliant devices presenting a risk to health and safety referred to in Article 68(2), (4) and (6);~~



- (b) ~~information in relation to compliant devices presenting a risk to health and safety referred to in Article 70(2);~~
  - (c) ~~information in relation to formal non-compliance of products referred to in Article 71(2);~~
  - (d) ~~information in relation to preventive health protection measures referred to in Article 72(2).~~
2. ~~The information mentioned in paragraph 1 shall be immediately transmitted through the electronic system to all competent authorities concerned and be accessible to the Member States and to the Commission.~~

#### *Article 67*

##### *Evaluation regarding devices **suspected to presenting an unacceptable risk or non-compliance to health and safety at national level***

Where the competent authorities of a Member State, based on ***data obtained by vigilance or market surveillance activities*** ~~data~~ or other information, have ~~sufficient~~ reason to believe that a device ***may*** presents ***an unacceptable*** risk to the health or safety of patients, users or other persons, ***or to other aspects of the protection of public health, or otherwise does not comply with the requirements laid down in this Regulation,*** they shall carry out an evaluation in relation to the device concerned covering all the requirements laid down in this Regulation that are relevant to the risk presented by ***or non-compliance of*** the device. The relevant economic operators shall cooperate ~~as necessary~~ with the competent authorities.

## Article 68

### Procedure for dealing with ~~non-compliant~~ devices presenting an **unacceptable** risk to health and safety

1. Where, having performed an evaluation pursuant to Article 67, the competent authorities find that the device, ~~which~~ presents an **unacceptable** risk to the health or safety of patients, users or other persons, **or to other aspects of the protection of public health and**, ~~does not comply with the requirements laid down in this Regulation~~, they shall without delay require the **manufacturer of the devices concerned, his authorised representatives and all other** relevant economic operators to take all appropriate and duly justified corrective action to bring the device into compliance with those requirements, to ~~prohibit or~~ restrict the making available of the device on the market, to subject the making available of the device to specific requirements, to withdraw the device from the market, or to recall it within a reasonable period, proportionate to the nature of the risk **or non-compliance**.
2. ~~Where~~ **The** competent authorities consider that non-compliance is not restricted to their national territory, they shall ~~inform~~ **notify** the Commission, and the other Member States **and the notified body that issued a certificate in accordance with Article 43 for the device concerned** of the results of the evaluation and of the actions which they have required the economic operators to take, by means of the electronic system referred to in Article ~~73b~~ **66**.
3. The economic operators shall ensure that all appropriate corrective action is taken in respect of all the devices concerned that they have made available on the market throughout the Union.

4. Where the relevant economic operator does not take adequate corrective action within the period referred to in paragraph 1, the competent authorities shall take all appropriate ~~provisional~~ measures to prohibit or restrict the device's being made available on their national market, to withdraw the device from that market or to recall it.

They shall notify the Commission, ~~and~~ the other Member States **and the notified body that issued a certificate in accordance with Article 43 for the device concerned**, without delay, of those measures, by means of the electronic system referred to in Article **73b 66**.

5. The notification referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification **and tracing** of the non-compliant device, the origin of the device, the nature of and the reasons for the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator.
6. Member States other than the Member State initiating the procedure shall, without delay, inform the Commission and the other Member States, **by means of the electronic system referred to in Article 73b**, of any additional **relevant** information at their disposal relating to the non-compliance of the device concerned and of any measures adopted by them in relation to the device concerned. In the event of disagreement with the notified national measure, they shall without delay inform the Commission and the other Member States of their objections, by means of the electronic system referred to in Article **73b 66**.
7. Where, within two months of receipt of the notification referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of **any** ~~provisional~~ measures taken by a Member State, ~~that~~ **those** measures shall be deemed **to be** justified.
8. ~~All~~ **Where paragraph 7 applies, all** Member States shall ensure that appropriate restrictive **or prohibitive** measures, **withdrawing, recalling or limiting the availability of the device on their national market** are taken without delay in respect of the device concerned.

## Article 69

### *Procedure for evaluating national measures at Union level*

1. Where, within two months of receipt of the notification referred to in Article 68(4), objections are raised by a Member State against a ~~provisional~~ measure taken by another Member State, or where the Commission considers the measure to be contrary to Union legislation, the Commission shall, ***after consulting the concerned competent authorities and, where necessary, the concerned economic operators***, evaluate the national measure. On the basis of the results of that evaluation, the Commission ~~shall~~ ***may*** decide, by means of implementing acts, whether or not the national measure is justified. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article ~~84~~**86**(3).
  
2. If the national measure is considered justified, Article 68(8) shall apply. If the national measure is considered unjustified, the Member State concerned shall withdraw the measure. ***In the absence of a Commission decision the national measures shall be considered to be justified.***
  
- 2a. Where, ~~in the situations referred to in Articles 68 and 70~~, a Member State or the Commission consider that the risk to health and safety emanating from a device cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned, the Commission, at the request of a Member State or on its own initiative, may take, by means of implementing acts, the necessary and duly justified measures to ensure the protection of health and safety, including measures restricting or prohibiting the placing on the market and putting into service of the device concerned. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).
  
3. ~~On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission shall adopt immediately applicable implementing acts referred to in paragraphs 1 and 2 in accordance with the procedure referred to in Article 84 (4).~~

*Article 70*

*Procedure for dealing with compliant devices presenting a risk to health and safety*

1. ~~Where, having performed an evaluation pursuant to Article 67, a Member State finds that although a device has been legally placed on the market or put into service, it presents a risk to the health or safety of patients, users or other persons or to other aspects of the protection of public health, it shall require the relevant economic operator or operators to take all appropriate provisional measures to ensure that the device concerned, when placed on the market or put into service, no longer presents that risk, to withdraw the device from the market or to recall it within a reasonable period, proportionate to the nature of the risk.~~
2. ~~The Member State shall immediately notify the Commission and the other Member States of the measures taken, by means of the electronic system referred to in Article 66. That information shall include the data necessary for the identification of the device concerned, the origin and the supply chain of the device, the findings of the Member State's evaluation specifying the nature of the risk involved and the nature and duration of the national measures taken.~~
3. ~~The Commission shall evaluate the provisional national measures taken. On the basis of the results of that evaluation, the Commission shall decide, by means of implementing acts, whether or not the measure is justified. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3). On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 84(4).~~
4. ~~Where the national measure is considered justified, Article 68(8) shall apply. If the national measure is considered unjustified, the Member State concerned shall withdraw the measure.~~  
*In the absence of a Commission decision the national measures shall be considered to be justified.*

## Article 71

### Formal non-compliance

1. **Where, having performed an evaluation pursuant to Article 67, ~~Without prejudice to Article 68~~ the competent authorities of a Member State find that a device does not comply with the requirements laid down in this Regulation but does not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, they shall require the relevant economic operator to put an end to the non-compliance concerned within a reasonable period that is proportionate to the non-compliance. ~~where it makes one of the following findings:~~**
  - (a) ~~that the CE marking has been affixed in violation of the formal requirements laid down in Article 16;~~
  - (b) ~~that the CE marking has not been affixed to a device contrary to Article 16;~~
  - (c) ~~that the CE marking has been inappropriately affixed in accordance with procedures in this Regulation on a product that is not covered by this Regulation;~~
  - (d) ~~that the EU declaration of conformity has not been drawn up or is not complete;~~
  - (e) ~~that the information to be supplied by the manufacturer on the label or in the instructions for use is not available, not complete or not provided in the language(s) required;~~
  - (f) ~~that the technical documentation, including the clinical evaluation, is not available or not complete.~~
2. Where the economic operator does not put an end to the non-compliance within the period referred to in paragraph 1, the Member State concerned shall take all appropriate measures to restrict or prohibit the product being made available on the market or to ensure that it is recalled or withdrawn from the market. That Member State shall inform the Commission and the other Member States without delay of those measures, by means of the electronic system referred to in Article ~~73b~~ 66.
3. **The Commission may, by means of implementing acts, elaborate details on the nature of non-compliances and appropriate measures to be taken by competent authorities to ensure the uniform application of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 86(3).**

## Article 72

### Preventive health protection measures

1. Where a Member State, after having performed an evaluation, which indicates a potential-risk related to a device or a specific category or group of devices considers that, ***in order to protect the health and safety of patients, users or other persons or other aspects of public health***, the making available on the market or putting into service of ~~such a~~ ***a*** device or ***a*** specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or category or group of devices should be withdrawn from the market or recalled ~~in order to protect the health and safety of patients, users or other persons or other aspects of public health~~, it may take any necessary and justified ~~provisional~~ measures.
2. The Member State shall immediately notify the Commission and all other Member States, giving the reasons for its decision, by means of the electronic system referred to in Article ***73b*** ~~66~~.
3. The Commission, ***in consultation with the MDCG and, where necessary, the concerned economic operators***, shall assess the ~~provisional~~ national measures taken. The Commission ~~shall~~ ***may*** decide, by means of implementing acts, whether the national measures are justified or not. ***In the absence of a Commission decision the national measures shall be considered to be justified***. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

~~On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission may adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 84(4).~~

4. Where the assessment referred to in paragraph 3 demonstrates that the making available on the market or putting into service of a device, specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or category or group of devices should be withdrawn from the market or recalled in all Member States in order to protect the health and safety of patients, users or other persons or other aspects of public health, the Commission ~~shall be empowered to~~ **may** adopt ~~delegated~~ **implementing** acts in accordance with **the examination procedure referred to in** Article ~~85~~ **84(3)** to take the necessary and duly justified measures.

~~Where in this case imperative grounds of urgency so require, the procedure provided for in Article 86 shall apply to delegated acts adopted pursuant to this paragraph.~~

### *Article 73*

#### *Good administrative practice*

1. Any measure adopted by the competent authorities of the Member States pursuant to Articles 68 to 72 shall state the exact grounds on which it is based. Where it is addressed to a specific economic operator, it shall be notified without delay to the economic operator concerned, who shall at the same time be informed of the remedies available to him under the law **or the administrative practice** of the Member State concerned and of the time limits to which such remedies are subject. Where the measure is of general scope, it shall be appropriately published.
2. Except in cases where immediate action is necessary for reasons of serious risk to human health or safety, the economic operator concerned shall be given the opportunity to make submissions to the competent authority within an appropriate period of time before any measure is adopted. If action has been taken without the economic operator's being heard, he shall be given the opportunity to make submissions as soon as possible and the action taken shall be reviewed promptly thereafter.



3. Any measure adopted shall be immediately withdrawn or amended upon the economic operator's demonstrating that he has taken effective corrective action ***and that the device is in compliance with the requirements of this Regulation.***
4. Where a measure adopted pursuant to Articles 68 to 72 concerns a product for which a notified body has been involved in the conformity assessment, the competent authorities shall ***by means of the electronic system referred to in Article 73b*** inform the relevant notified body ***and the authority responsible for the notified body*** of the measure taken.

#### *Article 73b 66*

##### *Electronic system on market surveillance*

1. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process the following information: -
  - (aa) summaries of the results of the surveillance activities referred to in Article 67(1c);***
  - (a) information in relation to non-compliant devices presenting a risk to health and safety referred to in Article 68(2), (4) and (6);
  - ~~(b) information in relation to compliant devices presenting a risk to health and safety referred to in Article 70(2);~~
  - (c) information in relation to formal non-compliance of products referred to in Article 71(2);
  - (d) information in relation to preventive health protection measures referred to in Article 72(2);
  - (e) summaries of the results of the reviews and assessments of the surveillance activities of the Member States referred to in Article 65(2).***
2. The information mentioned in paragraph 1 shall be immediately transmitted through the electronic system to all competent authorities concerned ***and, where applicable, to the notified body that issued a certificate in accordance with Article 43 for the device concerned*** and be accessible to the Member States and to the Commission.

3. *Information exchanged between Member States shall not be made public when this may impair market surveillance activities and co-operation between Member States.*

## Chapter VIII

### Cooperation between Member States, Medical Device Coordination Group, EU reference laboratories, device registers

#### Article 74

##### Competent authorities

1. The Member States shall designate the competent authority or authorities responsible for the implementation of this Regulation. They shall entrust their authorities with the powers, resources, equipment and knowledge necessary for the proper performance of their tasks pursuant to this Regulation. The Member States shall communicate ***the names and contact details of*** the competent authorities to the Commission which shall publish a list of competent authorities.
- ~~2. For the implementation of Articles 48 to 58, the Member States may designate a national contact point other than a national authority. In this case, references to a competent authority in this Regulation shall be understood as including the national contact point.~~

#### Article 75

##### Cooperation

1. The competent authorities of the Member States shall cooperate with each other and with the Commission ***which shall provide for the organisation of exchanges of*** ~~and exchange with each other the~~ information necessary to enable this Regulation to be applied uniformly.
2. Member States ***shall with the support of*** ~~and~~ the Commission shall participate, ***where appropriate*** in initiatives developed at international level with the aim of ensuring cooperation between regulatory authorities in the field of medical devices.

## Article 76

### Medical Device Coordination Group

The Medical Device Coordination Group (MDCG) established in accordance with the conditions and modalities defined in Article 78; **and 82** of Regulation (EU) [Ref. of future Regulation on medical devices] shall carry out, with the support of the Commission as provided in Article 79 of that Regulation, the tasks assigned to it by this Regulation.

## Article 77

### Tasks of the MDCG

The MDCG shall have the following tasks:

- (a) to contribute to the assessment of applicant conformity assessment bodies and notified bodies pursuant to the provisions set out in Chapter IV;
- (b) to contribute to the scrutiny of certain conformity assessments pursuant to Article 42;
- (c) to contribute to the development of guidance aimed at ensuring effective and harmonised implementation of this Regulation, in particular regarding the designation and monitoring of notified bodies, application of the general safety and performance requirements and conduct of the clinical evaluation by manufacturers, ~~and~~ the assessment by notified bodies **and the vigilance activities**;
- (ca) to contribute to the to the continuous monitoring of the technical progress and assessment whether the general safety and performance requirements in this Regulation and Regulation (EU) No [.../...] [on medical devices] are appropriate to ensure safety and performance of in vitro diagnostic medical devices and identify the need to amend Annex I;**
- (cb) to contribute to the development of in vitro diagnostic medical devices standards and of Common Specifications;**
- (d) to assist the competent authorities of the Member States in their coordination activities in **particular in the fields of classification and regulatory status of in vitro diagnostic medical devices**, clinical performance studies, vigilance and market surveillance **including the development and maintenance of a framework for a European market surveillance program with the objective of efficiency and harmonisation of market surveillance in the European Union, in accordance with Article 65;**

- (e) to provide advice ~~and assist the Commission~~, *either on its own initiative or* at its request *of the Commission*, in ~~its~~ *the* assessment of any issue related to the implementation of this Regulation;
- (f) to contribute to harmonised administrative practice with regard to *in vitro* diagnostic medical devices in the Member States.

## *Article 78*

### *European Union reference laboratories*

1. For specific devices, or a category or group of devices, or for specific hazards related to a category or group of devices, the Commission may designate, by means of implementing acts, one or more European Union reference laboratories, hereinafter referred to as 'EU reference laboratories', that satisfy the criteria set out in paragraph 3. The Commission shall only designate laboratories for which a Member State or the Commission's Joint Research Centre have submitted an application for designation.
2. Within the scope of their designation, the EU reference laboratories shall, where appropriate, have the following tasks:
  - (a) to verify compliance of class D ~~and class C~~ devices with the applicable CTS, ~~when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent, as provided for in the second subparagraph of Article 40(2);~~
  - (b) to carry out appropriate tests on samples of manufactured class D devices or batches of class D devices, as provided for in the Section 5.7 of Annex VIII and in Section 5.1 of Annex X;
  - (c) to provide scientific and technical assistance to the Commission, *the MDCG* the Member States and notified bodies in relation to the implementation of this Regulation;
  - (d) to provide scientific advice regarding the state of the art in relation to specific devices, or a category or group of devices;

- (e) to set up and manage a network of national reference laboratories ***after consulting with the national authorities*** and publish a list of the participating national reference laboratories and their respective tasks;
- (f) to contribute to the development of appropriate testing and analysis methods to be applied for conformity assessment procedures and market surveillance;
- (g) to collaborate with notified bodies in the development of best practices for the performance of conformity assessment procedures;
- (h) to provide recommendations on suitable reference materials and reference measurement procedures of higher metrological order;
- (i) to contribute to the development of standards at international level;
- (j) to provide scientific opinions in response to consultations by notified bodies in accordance with this Regulation ***and publish them by electronic means after consideration of national provisions on the respect of confidentiality.***

***2a. At the request of a Member State, the Commission may also designate EU reference laboratories where that Member State wishes to have recourse to such a laboratory to ensure the verification of the compliance of Class C devices with the applicable CS when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent.***

3. EU reference laboratories shall satisfy the following criteria:

- (a) to have ***adequate and*** appropriately qualified staff with adequate knowledge and experience in the field of the *in vitro* diagnostic medical devices for which they are designated;
- (b) to possess the necessary equipment and reference material to carry out the tasks assigned to them;
- (c) to have the necessary knowledge of international standards and best practices;
- (d) to have an appropriate administrative organisation and structure;
- (e) to ensure that their staff observe the confidentiality of the information and data obtained in carrying out their tasks;

- (f) to act in the public interest and in an independent manner;
- (g) to ensure that their staff do not have financial or other interests in the in vitro diagnostic medical device industry which could affect their impartiality, declare any other direct and indirect interests they may have in the in vitro diagnostic medical device industry and update this declaration whenever a relevant change occurs.

**3a. *The network of European Union reference laboratories shall satisfy the following criteria and the reference laboratories in the network shall coordinate and harmonise their working methods as regards testing and assessment. This involves:***

- (a) applying coordinated methods, procedures and processes;***
- (b) agreeing on the use of same reference materials and common test samples and seroconversion panels;***
- (c) establishing and common assessment and interpretation criteria;***
- (d) using common testing protocols and assessing the test results using standardised and coordinated evaluation methods;***
- (e) using standardised and coordinated test reports;***
- (f) developing, applying and maintaining a peer review system;***
- (g) organizing regular quality assessment tests (including mutual checks on the quality and comparability of test results);***
- (h) agreeing on joint guidelines, instructions, procedural instructions or standard operational procedures (SOPs);***
- (i) coordinating the introduction of testing methods for new technologies and according to new or amended CS;***
- (j) reassessing the state of the art on the basis of comparative test results or by further studies, as requested by the Commission or a Member State;***

4. EU reference laboratories may be granted a Union financial contribution.

The Commission may adopt, by means of implementing acts, the modalities and the amount of the grant of a Union financial contribution to EU reference laboratories, taking into account the objectives of protection of health and safety, support of innovation and cost-effectiveness. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).

5. Where notified bodies or Member States request scientific or technical assistance or a scientific opinion from an EU reference laboratory, they may be required to pay fees to wholly or partially cover the costs incurred by that laboratory in carrying out the requested task according to a set of predetermined and transparent terms and conditions.
6. The Commission shall ~~specify~~ ~~be empowered to~~ **by means of** ~~adopt delegated~~ **implementing** acts in accordance with Article 84~~5~~ for the following purposes:
  - (a) ~~amending, or supplementing~~ **detailed rules to facilitate the application** ~~the tasks of EU reference laboratories referred to in~~ **of** paragraph 2 and **detailed rules to ensure compliance with** the criteria ~~to be satisfied by EU reference laboratories referred to in~~ paragraph 3.
  - (b) setting out the structure and the level of the fees referred to in paragraph 5 which may be levied by an EU Reference Laboratory for providing scientific opinions in response to consultations by notified bodies **and Member States** in accordance with this Regulation, taking into account the objectives of protection of human health and safety, support of innovation and cost-effectiveness.
7. EU reference laboratories shall be subject to controls, including on-site visits and audits, by the Commission to verify compliance with the requirements of this Regulation. If these controls find that a laboratory is not complying with those requirements for which they have been designated, the Commission, by means of implementing acts' shall take appropriate measures, including the **restriction, suspension or** withdrawal of the designation.



*Article 79*

*Device registers and data banks*

The Commission and the Member States shall take all appropriate measures to encourage the establishment of registers *and data banks* for specific types of devices ~~to gather post-market experience related to the use of such devices~~ ***setting common principles to collect comparable information.*** Such registers *and data banks* shall contribute to the independent evaluation of the long-term safety and performance of devices.

## Chapter IX

### Confidentiality, data protection, funding, penalties

#### *Article 80*

#### *Confidentiality*

1. Unless otherwise provided in this Regulation and without prejudice to existing national provisions and practices in the Member States on ~~medical~~ confidentiality, all parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the following:
  - (a) personal data in compliance with *Article 81* ~~Directive 95/46/EC and Regulation (EC) No 45/2001~~;
  - (b) commercial interests *and trade secrets* of a natural or legal person, including intellectual property rights *unless disclosure is necessary for reasons of public health*;
  - (c) the effective implementation of this Regulation, in particular for the purpose of inspections, investigations or audits.
2. Without prejudice to paragraph 1, information exchanged between competent authorities and between competent authorities and the Commission on condition of confidentiality shall ~~remain confidential unless~~ **shall not be disclosed without prior consultation with** the originating authority ~~has agreed to its disclosure~~.
3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States and notified bodies with regard to exchange of information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.
4. The Commission and Member States may exchange confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements.

*Article 81*

*Data protection*

1. Member States shall apply Directive 95/46/EC to the processing of personal data carried out in the Member States pursuant to this Regulation.
2. Regulation (EC) No 45/2001 shall apply to the processing of personal data carried out by the Commission pursuant to this Regulation.

*Article 82*

*Levy of fees*

1. This Regulation shall be without prejudice to the possibility for Member States to levy fees for the activities set out in this Regulation, provided that the level of the fees is set in a transparent manner and on the basis of cost recovery principles. ~~They~~
2. **Member States** shall inform the Commission and the other Member States at least three months before the structure and level of fees is to be adopted.

*Article 38 82a*

*Fees Funding of notified body designation and monitoring activities*

- ~~1. The Member State where the bodies are established shall levy fees on applicant conformity assessment bodies and on notified bodies. These fees shall, wholly or partly, cover the costs relating to the activities exercised by the national authorities responsible for notified bodies in accordance with this Regulation.~~
- 1a. **The cost associated with the joint assessment activities shall be covered by the Commission. The Commission shall lay down the scale and structure of recoverable costs and other necessary implementing rules. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).**

2. ~~The Commission shall be empowered to adopt delegated acts in accordance with Article 85 setting out the structure and the level of the fees *relating to joint assessment activities* referred to in paragraph 1 *and the attribution of costs referred to in paragraph 1a*, taking into account the objectives of protection of human health and safety, support of innovation and cost effectiveness. Particular attention shall be paid to the interests of notified bodies that received a certificate delivered by the national accreditation body as referred to in Article 29(2) and notified bodies that are small and medium-sized enterprises as defined by Commission Recommendation 2003/361/EC.~~

### *Article 83*

#### *Penalties*

The Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate, and dissuasive. The Member States shall notify those provisions to the Commission by [*3 months prior to the date of application of the Regulation*] and shall notify it without delay of any subsequent amendment affecting them.

## Chapter X

### Final provisions

#### *Article 84*

##### *Committee procedure*

1. The Commission shall be assisted by the Committee on Medical Devices set up by Article 88 of Regulation (EU) [*Ref. of future Regulation on medical devices*].
2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.
3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

***Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.***

4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 4 or Article 5, as appropriate, shall apply.

#### *Article 85*

##### *Exercise of the delegation*

1. The power to adopt the delegated acts referred to in Articles 4(6), 8(2), 15(4), 22(7a), ~~23(7)~~, ~~27(2)~~, ~~38(2)~~, ~~39(4)~~, 40(10), 43(5), ~~49(7)~~, ~~51(3)~~, ~~72(4)~~ and ~~78(6)~~ **78a(10)** is conferred on the Commission subject to the conditions laid down in this Article. ***When adopting those delegated acts, the Commission shall follow its usual practice and carry out consultations with experts, including Member States' experts.***

2. The delegation of power referred to in Articles 4(6), 8(2), 15(4), 22(7a), ~~23(7), 27(2), 38(2), 39(4), 40(10), 43(5), 49(7), 51(3), 72(4) and 78(6)~~ **78a(10)** shall be conferred on the Commission for ~~an indeterminate period of time~~ **a period of five years** from the date of entry into force of this Regulation. ***The Commission shall draw up a report in respect of the delegated powers not later than six months before the end of the five year period. The delegation of powers shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.***
3. The delegation of power referred to in Articles 4(6), 8(2), 15(4), 22(7a), ~~23(7), 27(2), 38(2), 39(4), 40(10), 43(5), 49(7), 51(3), 72(4) and 78(6)~~ **78a(10)** may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following its publication in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
5. A delegated act adopted pursuant to any of the Articles listed in paragraph 1 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of ~~two~~ **three** months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period may be extended by ~~two~~ **three** months at the initiative of the European Parliament or the Council.

## *Article 86*

### *Urgency procedure for delegated acts*

- ~~1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.~~
- ~~2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 85. In such a case, the Commission shall repeal the act without delay following the notification of the decision to object by the European Parliament or the Council.~~

## *Article 86a*

### *Separate delegated acts for different delegated powers*

***The Commission shall adopt a separate delegated act in respect of each power delegated to it pursuant to this Regulation.***

## *Article 87*

### *Transitional provisions*

1. From the date of application of this Regulation any publication of a notification in respect of a notified body in accordance with Directive 98/79/EC shall become void.
2. Certificates issued by notified bodies in accordance with Directive 98/79/EC prior to the entry into force of this Regulation shall remain valid until the end of the period indicated on the certificate, except for certificates issued in accordance with Annex VI of Directive 98/79/EC which shall become void at the latest two years after the date of application of this Regulation.

Certificates issued by notified bodies in accordance with Directive 98/79/EC after the entry into force of this Regulation shall become void at the latest two years after the date of application of this Regulation.

3. By way of derogation from Directive 98/79/EC, devices which comply with this Regulation may be placed on the market before its date of application.
4. By way of derogation from Directive 98/79/EC, conformity assessment bodies which comply with this Regulation may be designated and notified before its date of application. Notified bodies which are designated and notified in accordance with this Regulation may apply the conformity assessment procedures laid down in this Regulation and issue certificates in accordance with this Regulation before its date of application.
5. By way of derogation from Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC, manufacturers, authorised representatives, importers and notified bodies who, during the period from [date of application] until [18 months after date of application], comply with Article 23(2) and (3) and Article 43(4) of this Regulation shall be considered to comply with the laws and regulations adopted by Member States in accordance with Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC as specified in Commission Decision 2010/227/EU.
6. Authorisations granted by competent authorities of the Member States in accordance with Article 9(12) of Directive 98/79/EC shall keep the validity indicated in the authorisation.
7. ***Until the Commission in line with Article 24 (2) has designated the UDI assigning entities, GS1 AISBL, HIBCC and ICCBBA shall be considered as designated UDI assigning entities.***

#### *Article 88*

#### *Evaluation*

No later than five years after the date of application, the Commission shall assess the application of this Regulation and establish an evaluation report on the progress towards achievement of the objectives of ~~the~~ this Regulation including an assessment of resources required to implement this Regulation.



## Article 89

### Repeal

Directive 98/79/EC of the European Parliament and of the Council is repealed with effect from [date of application of this Regulation] with the exception of Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC which are repealed with effect from [18 months after date of application].

References to the repealed Directive shall be understood as reference to this Regulation and shall be read in accordance with the correlation table laid down in Annex XIV.

## Article 90

### Entry into force and date of application

1. This Regulation shall enter into force on the twentieth day after its publication in the *Official Journal of the European Union*.
2. It shall apply from [five years after entry into force].
3. By way of derogation from paragraph 2 the following shall apply:
  - (a) Article 23(2) and (3) and Article 43(4) shall apply from [18 months after date of application referred to in paragraph 2];
  - (b) Articles 26 to 38 shall apply from [six months after entry into force]. However, prior to [date of application as referred to in paragraph 2], the obligations on notified bodies emanating from the provisions in Articles 26 to 38 shall apply only to those bodies which submit an application for notification in accordance with Article 29 of this Regulation.
  - (c) **For class D devices Article 22(4) shall apply one year after the date of application of this regulation. For class B and class C devices Article 22(4) shall apply three years after the date of application of this regulation. For class A devices Article 22(4) shall apply five years after the date of application of this regulation.**

*(d) Articles 22 to 25, Chapter VI, Article 58c(2), Article 63a and Article 64a shall apply from six months after the publication of the notice referred to in Article 27a(3) of Regulation [future regulation on Medical devices], but in any event no earlier than the period referred to in paragraph 2.*

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, ~~26.9.2012~~

*For the European Parliament*

*For the Council*

*The President*

*The President*

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