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Interinstitutional File:  
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12042/15  
COR 1

PHARM 37  
SAN 282  
MI 568  
COMPET 411  
CODEC 1194

**NOTE**

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From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
No. Cion doc.:	14499/12 PHARM 72 SAN 216 MI 598 COMPET 599 CODEC 2312 + COR 1
Subject:	Proposal for a Regulation of the European Parliament and of the Council on <i>in vitro</i> diagnostic medical devices

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On page 30, for:

"(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;*"

read:

"(8aa) *'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;*".

On page 34, for:

"(33) ~~clinical~~ performance study' means a study undertaken to establish or confirm the clinical performance of a device;"

read:

"(33) ~~clinical~~ performance study' means a study undertaken to establish or confirm the analytical or clinical performance of a device;"

On page 35, in point (37a) for:

" *and/or by a control*;"

read:

" *and/or by a device used for control purposes*".

On page 52, for:

"(c) cooperate with the competent authorities on any corrective action taken to eliminate *or, if that is not possible, mitigate* the risks posed by devices;"

read:

"(c) cooperate with the competent authorities on any preventive or corrective action taken to eliminate *or, if that is not possible, mitigate* the risks posed by devices;"

On page 80, for:

"(aa) *the electronic system on registration of devices referred to in Article 24b*;"

read:

"(aa) *the electronic system on registration of devices referred to in Article 22b*;"

On page 194, on the sixth line of paragraph 5, for:

" That period ~~may~~ be extended by ..."

read:

" That period ~~may~~ shall be extended by ...".

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