



Council of the
European Union

Brussels, 2 October 2015
(OR. en)

Interinstitutional File:
2012/0267 (COD)

12042/15
COR 1

PHARM 37
SAN 282
MI 568
COMPET 411
CODEC 1194

NOTE

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 *in vitro* diagnostic medical devices

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 ...".
