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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 …".