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NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
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Subject:	Proposal for a Regulation of the European Parliament and of the Council on ***in vitro*** **diagnostic medical devices**

On page 21, for

"(vii) ~~Where applicable,~~ the unique device identification (UDI) ***carrier according to Article 24 and Annex V Part C***;"

read

"(vii) ~~Where applicable,~~ the unique device identification (UDI) ***carrier according to Article 22 and Annex V Part C***;".

On page 24, for

"- ***for companion diagnostics, the INN (International Non-proprietary Name) of the associated drug for which it is a companion test.***"

read

"- ***for companion diagnostics, the INN (International Non-proprietary Name) of the associated medicinal product for which it is a companion test.***".

On page 29, for

" ***In the case of the following devices, other…***"

read:

"***<u>17.3.1a.</u>*** ***In the case of the following devices, other…***".

On page 42, for

"***a post-market performance follow-up plan according to Part B of Annex XII, or a justification why a post-market performance follow-up is not <u>deemed necessary or appropriate</u>.***"

read

"***a post-market performance follow-up plan according to Part B of Annex XII, or a justification why a post-market performance follow-up is not <u>applicable</u>.***".

On page 45, for

" **Information to be submitted with the registration of devices in accordance with Article 23*a*** "

read

"**Information to be submitted with the registration of devices *<u>and economic operators</u>* in accordance with Article 23*a***".