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WORKING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices - Medical Devices
N° Cion doc.:	14493/12 PHARM 71 SAN 215 MI 597 COMPET 600 CODEC 2305 + COR 1 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 medical devices and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 Proposal for a Regulation of the European Parliament and of the Council on in vitro diagnostic medical devices

Delegations will find in this document comments regarding the two proposed Regulations put forward by the French delegation.

Content of the document:

Consolidated text on MD regulation (ST 9238/15) :

- On page 10, Article 2 (1) (15b), the terminology of “*safe*” is not consistent with the one used in the consolidated document on IVD regulation in page 7, Article 2(1)(15a) (“*safety*”) ;
- On page 31, Article 9(4), there is a reference to Article 8(3a) which doesn’t exist anymore ;
- On page 93, Article 35a (3), the term “*technical*” should be deleted as followed “*common technical specifications*”.

ST 9238/15 ADD 1 :

- On page 11, Annex I (9), the wording is not aligned with the one used in other provisions on the same products (Annex I (9.2), 19.2(r), annex VII,6.9 (rule 21) and annex VIII (6.3)) ;
- On page 24, Annex I, 19.2(d), the wording should be corrected ;
- On page 42, Annex V, part A, the title is not aligned with the one used in the consolidated document on IVD regulation in page 43 : need for consistency between the 2 annexes.

Consolidated text on IVD regulation (ST 9239/15) :

- On page 10, Article 2 (1) (34), the definition of “*clinical performance study plan*” is not aligned with the definition of “*clinical investigation plan*” laid down in the consolidated document on MD regulation in page 14 Article 2(1)(35) ;
- On pages 90-91, Article 42, the end of the original text hasn’t been deleted ;
- On page 99, Article 48(2), the word “*performance*” appears two times: one reference should be deleted.

ST 9238/15 ADD 1 :

- On page 94, Annex VII, 2.5(a), punctuation marks are missing, notably between the words « *no critical characteristics* » and « *buffer solutions* » (add at least a comma or “such as”..)
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