



Council of the  
European Union

Brussels, 24 February 2017  
(OR. en)

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2012/0266 (COD)**

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COR 1**

**PHARM 43  
SAN 284  
MI 478  
COMPET 402  
CODEC 977**

### **LEGISLATIVE ACTS AND OTHER INSTRUMENTS**

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Subject: Position of the Council at first reading with a view to the adoption of a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

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On page 127, in Article 29(3):

For:

"3. For devices that are the subject of a conformity assessment as referred to in the second sentence of Article 52(3), or the third subparagraph of Article 52(4), the assignment of a Basic UDI-DI..."

read:

"3. For devices that are the subject of a conformity assessment as referred to in Article 52(3) and in the second and third subparagraphs of Article 52(4), the assignment of a Basic UDI-DI..."