



Council of the
European Union

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LEGISLATIVE ACTS AND OTHER INSTRUMENTS

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 *in vitro* diagnostic medical devices and repealing
Directive 98/79/EC and Commission Decision 2010/227/EU

On page 100, in Article 26(2):

For:

"2. For devices that are the subject of a conformity assessment as referred to in Article 48(4)
and 48(8), the assignment of a Basic UDI-DI...",

read:

"2. For devices that are the subject of a conformity assessment as referred to in Article 48(3)
and (4), the second subparagraph of Article 48(7), Article 48(8) and the second
subparagraph of Article 48(9), the assignment of a Basic UDI-DI...".