Amendment 354
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on behalf of the Verts/ALE Group

Report **A7-0324/2013**
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Medical devices
COM(2012)0542 – C7-0318/2012 – 2012/0266(COD)

Proposal for a regulation
Article 2 – paragraph 1 – subparagraph 1 – point 10

Text proposed by the Commission	*Amendment*
(10) 'intended purpose' means the use for which the device is intended according to the ***data supplied by the manufacturer on the*** label, in the instructions for use ***or*** in promotional or sales materials or statements;	(10) 'intended purpose' means the use for which the device is intended according to the ***clinical evaluation, to be reflected in the conformity certificate, the product*** label, in the instructions for use ***and if applicable*** in promotional or sales materials or statements;

Or. en

Justification

At present, several medical devices coming onto the market appear to have an intended purpose that is much wider than originally assessed in the clinical evaluation. The intended purpose must clearly reflect the mode of action of the device, the body location where the device should be used or implanted, and the disease indication including, where applicable, the disease stage. Otherwise, patient safety risks to be endangered.

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