Amendment 378
Mairead McGuinness, Peter Liese
on behalf of the PPE Group

Report
Dagmar Roth-Behrendt
Medical devices
COM(2012)0542 – C7-0318/2012 – 2012/0266(COD)

Proposal for a regulation
Annex I – Part I – point 6 a (new)

Text proposed by the Commission

6a. This Regulation now combines active implantable medical devices covered by Directive 90/385/EEC, and implantable medical devices covered by Directive 93/42/EEC, and places all active implantable medical devices and implantable devices of public health concern in the highest risk class III category attracting the strictest controls, and as the vast majority of class IIb implantable medical devices such as pins, bone-screws, plates, staples etc., have a long history of safe implantation within the human body, and as special notified bodies will be specifically designated for such class IIb implantable devices, class IIb implantable devices need not be subjected to the scrutiny procedure.

Amendment

Or. en
Amendment 379
Mairead McGuinness, Peter Liese
on behalf of the PPE Group

Report
Dagmar Roth-Behrendt
Medical devices
COM(2012)0542 – C7-0318/2012 – 2012/0266(COD)

Proposal for a regulation
Recital 42 a (new)

Text proposed by the Commission

(42a) As this Regulation now combines active implantable medical devices covered by Directive 90/385/EEC, and implantable medical devices covered by Directive 93/42/EEC, and places all active implantable medical devices and implantable devices of public health concern in the highest risk class III category attracting the strictest controls, and as the vast majority of class IIb implantable medical devices such as pins, bone-screws, plates, staples etc., have a long history of safe implantation within the human body, and as special notified bodies will be specifically designated for such class IIb implantable devices, class IIb implantable devices need not be subjected to the scrutiny procedure.

Or. en