



IMDRF

International Medical
Device Regulators Forum

Update on EU regulatory developments

Aurélien PEREZ

Team Leader

European Commission

Health Technology and Cosmetics

IMDRF – 5

25-27 March 2014

San Francisco, USA



IMDRF

International Medical
Device Regulators Forum

Revision of the EU Medical Devices Legislation -Background-



Directive 90/385/EEC on active implantable medical devices

Directive 93/42/EEC on medical devices



Proposal for a Regulation on medical devices



Directive 98/79/EC on *in vitro* diagnostic medical devices



Proposal for a Regulation on *in vitro* diagnostic medical devices



IMDRF

International Medical
Device Regulators Forum

Revision of the EU Medical Devices Legislation

-State of play-



- European Parliament vote on amendments and negotiation mandates : 22 October 2013
- European Parliament 1st reading vote : 3 April 2014 (tbc)
- Council : discussions on the proposals ongoing³



IMDRF

International Medical
Device Regulators Forum

Thank you for your attention !

Aurélien PEREZ

Team Leader

European Commission

Health Technology and Cosmetics