IMDRF International Medical Device Regulators Forum

European Commission

IMDRF – 4
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Update on EU regulatory developments

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European Commission

1. Revision of the EU Medical Devices Legislation

- Directive 90/385/EEC on active implantable medical devices
- Directive 93/42/EEC concerning medical devices
- Directive 98/79/EC on in vitro diagnostic medical devices

Proposals for a Regulation on medical devices and for a Regulation on in vitro diagnostic medical devices COM(2012)542 and COM(2012)541 final.

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2. EU Joint Plan for Immediate Action – new legal measures

1. Commission Recommendation (No 2013/172/EU) on a common framework for a unique device identification system of medical devices in the Union (5 April 2013, OJ L 99/17, 9.4.2013)
2. Commission Implementing Regulation (No 920/2013) on the designation and the supervision of notified bodies (24 September 2013, OJ L 253/8, 25.9.2013)
3. Commission Recommendation (No 2013/473/EU) on the audits and assessments performed by notified bodies in the field of medical devices (24 September 2013, OJ L 253/27, 25.9.2013)