



IMDRF

International Medical
Device Regulators Forum

Update on EU regulatory developments

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European Commission

Health Technology and Cosmetics

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The EU single market for medical devices



1. EU



2. EFTA/EEA:

Norway, Liechtenstein, Iceland



3. Turkey



4. Switzerland



Revision of the EU Medical Devices Legislation -Background-

Directive 90/385/EEC on active implantable medical devices

Directive 93/42/EEC on medical devices

Regulation on medical devices (MDR)

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

Regulation on *in vitro* diagnostic medical devices (IVDR)



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State of play and next steps

- April 2017: Final Adoption of the two new Regulations
- 5 May 2017: Publication of the two Regulations in the Official Journal of the EU
- To be progressively applied over the 3 years (MDR) and 5 years (IVDR) thereafter



The new regulatory framework in the field of medical devices is expected to ensure...

1. Better protection of public health and patient safety
2. Legal certainty and innovation-friendly environment
3. More transparency and patient empowerment
4. Better coordination at the EU level



Main features of the new texts (1)

- Stricter pre-market control of high-risk devices with the involvement of a pool of experts at EU level.
- Reinforcement of the criteria for designation and of the oversight processes of notified bodies in charge of certifying medical devices.
- Coverage of certain non-medical products (mainly aesthetics) which present the same characteristics and risk profile as analogous medical devices.
- Introduction of a new risk classification system for in-vitro diagnostic medical devices based on international guidance.
- Improved transparency through the establishment of a comprehensive EU database on medical devices.
- Stricter regime related to the use of hazardous substances



Main features of the new texts (2)

- Introduction of an EU-wide requirement for an “implant card” to be provided to patients containing information about implanted medical devices.
- Reinforcement of the rules on clinical investigation, including an EU-wide coordinated procedure for the authorisation of clinical investigation on medical devices taking place in more than one Member State.
- Reinforced requirements for manufacturers to collect and analyse data about the real-life use of their devices.
- Improved coordination between Member States in the fields of vigilance and market surveillance.
- The introduction of a UDI (Unique Device Identification) system and strengthening of the device traceability system.
- Role and responsibilities of economic operators. Certain new obligations for authorised representatives.



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Towards implementation



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Transitional period

May-
2017

May-
2020

May-
2022



**Publication of
Regulations in
Official
Journal of
European
Union and
entry into
force**



**Full
application of
MDR at 3
years (after
entry into
force)**



**Full
application of
IVDR at 5
years (after
entry into
force)**



Implementation: Commission priorities



Priorities

Notified Bodies (details of application, fees and reimbursements related to JAs) – Nov 2017

Governance: Setting up of the Medical Device Coordination Group (MDCG)* - Nov 2017

Common specification on devices without a medical purpose and reprocessing of single-use devices – date of application MDR - May 2020

EUDAMED – date of application MDR and IVDR – May 2020 and May 2022

*The MDCG is the main body supporting the Commission in implementing the future Regulations. It comprises representatives from National Authorities and is chaired by the Commission



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Thank you for your attention !

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