Update on EU regulatory developments

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The EU single market for medical devices

EU

EFTA/EEA
Norway, Liechtenstein, Iceland

Turkey

Switzerland*
EU legislation on medical devices

**Directive 90/385/EEC on active implantable medical devices (AIMDD)**

**Directive 93/42/EEC on medical devices (MDD)**


**Regulation (EU) 2017/745 on medical devices (MDR)** adopted in April 2017 and entered into force in May 2017, as amended – applicable from 26 May 2021

The two new regulations published in May

2017

2020

A one year delay of the MDR was adopted in April

2021

MDR date of application 26 May

2022

Amended transitional provisions for IVDR were adopted in January

2022

IVDR date of application 26 May

2022

26 May End of transitional period. All medical device directive certificates become void

2024

End of MDR transitional period 26 May

2025

26 May All IVDD certificates become void 26 May

2027

End of IVDR transitional period 26 May
IVDR transitional provisions

This visual depicts the transitional provisions for IVDs with a valid certificate or DoC issued prior to 26 May 2022 under the IVDD.

*for all new IVDs not previously placed under the IVDD, 26 May 2022 is the date of application.
COM implementation priorities (1)

Transition to MDR and IVDR

- MDCG 2022-14 position paper on notified body capacity and availability of medical devices and IVDs*
  1. Increase notified bodies’ capacities
  2. Facilitate access to notified bodies
  3. Other actions facilitating transition to MDR/IVDR and/or avoiding shortage of devices

Notified bodies

- 66 (50+16) applications received up to date. Full scope of MDR and IVDR covered
- 39 (32+7) notified bodies designated under MDR and IVDR*

Governance

- MDCG technical subgroups (13) operational as from 1st Mar 2019
- Work on 100+ guidance documents finalised with +40 ongoing*
COM implementation priorities (2)

Scientific Structures

• Expert panels designated (2019) and designated experts (Q1 2021)
• Expert panels running (Q2 2021) and number of opinions issued
• Transfer of expert panels to EMA (Q1 2022)*
• Call for EU reference laboratories (IVDR) (Q3 2022)*

Common Specifications/ Implementing Acts

• Reprocessing of single-use devices (Q3 2020)
• Devices without medical purpose (Annex XVI devices) (draft published Q2 2022)*
• Common specifications in accordance with Regulation (EU) 2017/746 (for Class D devices) (Q2 2022)*
• Commission Implementing Regulation (EU) 2022/944 on tasks and criteria for the EURLs (Q3 2022)*
• Commission Implementing Regulation (EU) 2022/945 on fees that the EURLs may levy from notified bodies and Member States (Q3 2022)*
COM implementation priorities (3)

**EUDAMED**
- Core actor registration module (Q4 2020) and UDI module (Q3 2021) made available
- Functional testing with users (ongoing)
- Preparations for full functionality audit (ongoing)

**UDI**
- 4 issuing entities designated and +15 guidance and factsheets published
- UDI helpdesk up & running (Q1 2021)
- Work on solutions for contact lenses and non-sterile surgical implants (ongoing)*

**Nomenclature**
- Published for public consultation (Q2 2021)
- Final version launched available in EN, IT, FR. Validations of remaining EU languages (ongoing)

**Standards**
- Mandate to Standardisation organisations published and accepted (Q2 2021)
- First list of harmonised standards published (Q3 2021), second list (Q1 2022), third list ongoing (Q2 2022)*
Key MDCG guidance published since January 2022

January 2022
- Notice to 3rd country manufacturers of SARS-CoV-2 in vitro diagnostic medical devices
- Guidance on general principles of clinical evidence for In Vitro Diagnostic medical devices (IVDs)
- Guidance on Classification Rules for in vitro Diagnostic Medical Devices under Regulation (EU) 2017/746

February 2022
- Verification of manufactured class D IVDs by notified bodies
- Guidance on appropriate surveillance regarding the transitional provisions under Article 120 of the MDR with regard to devices covered by certificates according to the MDD or the AIMDD

March 2022
- Summary of safety and clinical performance Rev.1

April 2022
- Guidance on borderline between medical devices and medicinal products under Regulation (EU) 2017/745 on medical devices

May 2022
- Q&A on the interface between Regulation (EU) 536/2014 on clinical trials for medicinal products for human use (CTR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)
- Summary of safety and performance template

- Regulation (EU) 2017/746 - application of IVDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2022 in accordance with Directive 98/79/EC
- Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR.
- Q&A on the Unique Device Identification system under Regulation (EU) 2017/745 and Regulation (EU)

June 2022
- MDCG Position Paper: Notice to manufacturers to ensure timely compliance with MDR requirements
- Guidance on harmonised administrative practices and alternative technical solutions until Eudamed is fully functional (for Regulation (EU) 2017/746 on in vitro diagnostic medical devices)

July 2022
- Designation, re-assessment and notification of conformity assessment bodies and notified bodies
- Transition to the MDR and IVDR - Notified body capacity and availability of medical devices and IVDs

August 2022
- MDCG guidance documents to support all actors, including manufacturers and notified bodies
Thank you

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Extra slides on IVDR transitional provisions
Amendment to IVDR transitional provisions

Date of application (26 May 2022) maintained

Extension of transitional provisions (scope and timelines):


- Devices with a Declaration of Conformity (DoC) under Directive 98/79/EC and requiring NB involvement under Regulation (EU) 2017/746 – risk-based approach
  - class D – provide transition period until 26 May 2025
  - class C – provide transition period until 26 May 2026
  - class B and class A sterile – provide transition period until 26 May 2027

In-house devices, i.e. those subject to Article 5(5) of Regulation (EU) 2017/746:
  - maintain the exemption as under Directive 98/79/EC from 26 May 2022
  - provide transition period until 26 May 2024 for requirements in Art. 5(5), points (b), (c), (e) – (i)
  - provide transition period until 26 May 2028 for requirement in Art. 5(5), point (d)