



Update on EU regulatory developments



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European Commission

IMDRF – 20

The EU single market for medical devices

EU



EFTA/EEA

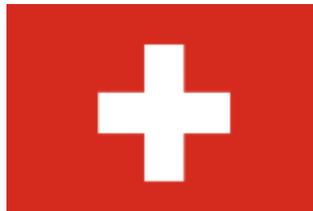
Norway, Liechtenstein, Iceland



Turkey



Switzerland*



EU legislation on medical devices

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

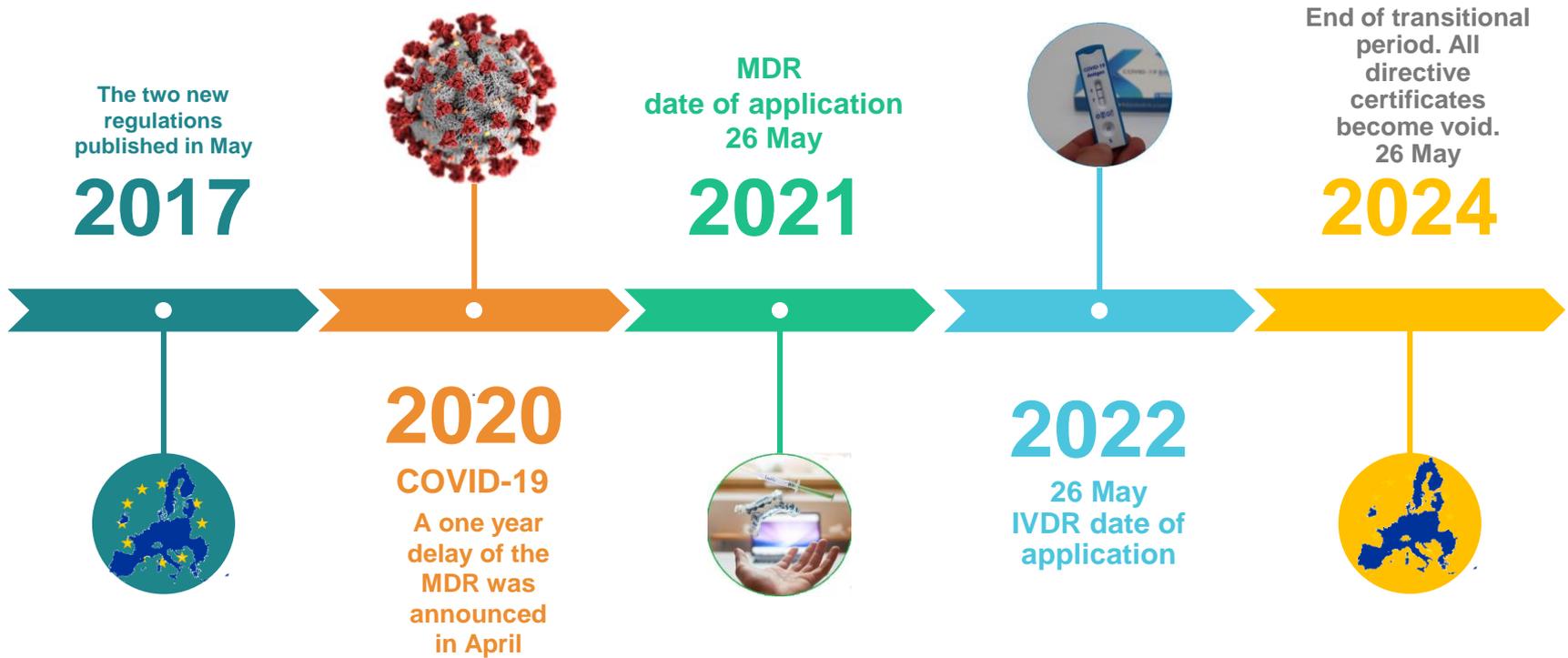
Directive 93/42/EEC on medical devices (MDD)

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

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

Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR) adopted in April 2017 and entered into force in May 2017, as amended – fully applicable from **26 May 2022**

Timelines



COM implementation priorities (1)

Notified bodies

- ✓ 66 (50+16) applications received up to date. Full scope of MDR and IVDR covered
- ✓ 28 (22+6) notified bodies designated under MDR and IVDR

Governance

- ✓ Set up of MDCG (November 2017)
- ✓ MDCG technical subgroups (13) operational as from 1st Mar 2019
- ✓ Work on 83+ guidance documents finalised with +30 ongoing

Scientific Structures

- ✓ Expert panels designated (2019) and designated experts (Q1 2021)
- ✓ Expert panels running (Q2 2021) and first opinion issued.
- ✓ Expert laboratories and reference labs (timelines under revision)

EUDAMED

- ✓ Core actor registration module made available (Q4 2020)
- ✓ UDI module (Q3 2021)

COM implementation priorities (2)

UDI

- ✓ 4 issuing entities designated & + 13 guidance and factsheets published
- ✓ UDI helpdesk up & running (Q1 2021)

Nomenclature

- ✓ Published for public consultation (Q2 2021)
- ✓ Final version launch ahead of UDI module go-live date

Standards

- ✓ Mandate to Standardisation organisations published & accepted (Q2 2021)
- ✓ First list of harmonised standards published (Q3 2021)

Common Specifications/ Implementing Acts

- ✓ Reprocessing of single-use devices (Q3 2020)
- ✓ Devices without medical purpose (Q3-Q4 2021)

Planning of activities:

- ✓ Publication of Commission's rolling plan on DG SANTE's website

COM implementation priorities (3) - Key guidance published since March 2021

March 2021

- ✓ Guidance on state of the art of COVID-19 rapid antibody tests
- ✓ Questions and Answers on Custom-Made Devices
- ✓ Is your software a Medical Device?

April 2021

- ✓ Regulation (EU) 2017/745 – Questions & Answers regarding clinical investigation
- ✓ Application of transitional provisions for certification of class D in vitro diagnostic medical devices according to Regulation (EU) 2017/746
- ✓ Guidance on standardisation for medical devices
- ✓ Guidance on basic UDI-DI and changes to UDI-DI

May 2021

- ✓ Clinical investigation application/notification documents
- ✓ Notice to manufacturers and authorised representatives on the impact of genetic variants on SARS-CoV-2 in vitro diagnostic medical devices
- ✓ Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional
- ✓ Guidance on Implant Card – Device types
- ✓ Position Paper on the implementation of UDI requirements for contact lenses, spectacle frames, spectacle lenses & ready readers

June 2021

- ✓ FAQ on the European Medical Device Nomenclature

- ✓ The status of Appendixes E-I of IMDRF N48 under the EU regulatory framework for medical devices
- ✓ Questions & Answers for applicants, marketing authorisation holders of medicinal products and notified bodies

July 2021

- ✓ Instructions for generating CIV-ID for MDR Clinical Investigations
- ✓ Questions and answers on obligations and related rules for the registration in EUDAMED of actors other than manufacturers, authorised representatives and importers subject to the obligations of Article 31 MDR and Article 28 IVDR
- ✓ Explanatory note on IVDR codes
- ✓ Guidance note integration of the UDI within an organisation's quality management system

August 2021

- ✓ Guidance on performance evaluation of SARS-CoV-2 in vitro diagnostic medical devices
- ✓ Clarification on “first certification for that type of device” and corresponding procedures to be followed by notified bodies, in context of the consultation of the expert panel referred to in Article 48(6) of Regulation (EU) 2017/746
- ✓ Guidance for notified bodies, distributors and importers on certification activities in accordance with Article 16(4) of Regulation (EU) 2017/745 and Regulation (EU) 2017/746

Thank you for your attention !

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