IMDRF International Medical Device Regulators Forum

Update on EU regulatory developments

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European Commission

IMDRF-22

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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)

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 – applicable from **26 May 2021**

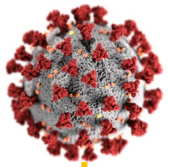
→ **Regulation (EU) 2017/746 on on *in vitro* diagnostic medical devices (IVDR)** adopted in April 2017 and entered into force in May 2017, as amended – applicable from **26 May 2022**

Timelines

The two new regulations published in May **2017**

2020

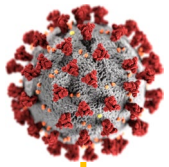
A one year delay of the MDR was adopted in April



MDR date of application 26 May **2021**

2022

Amended transitional provisions for IVDR were adopted in January



IVDR date of application 26 May **2022**

2022

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

End of MDR transitional period 26 May **2024**

2025

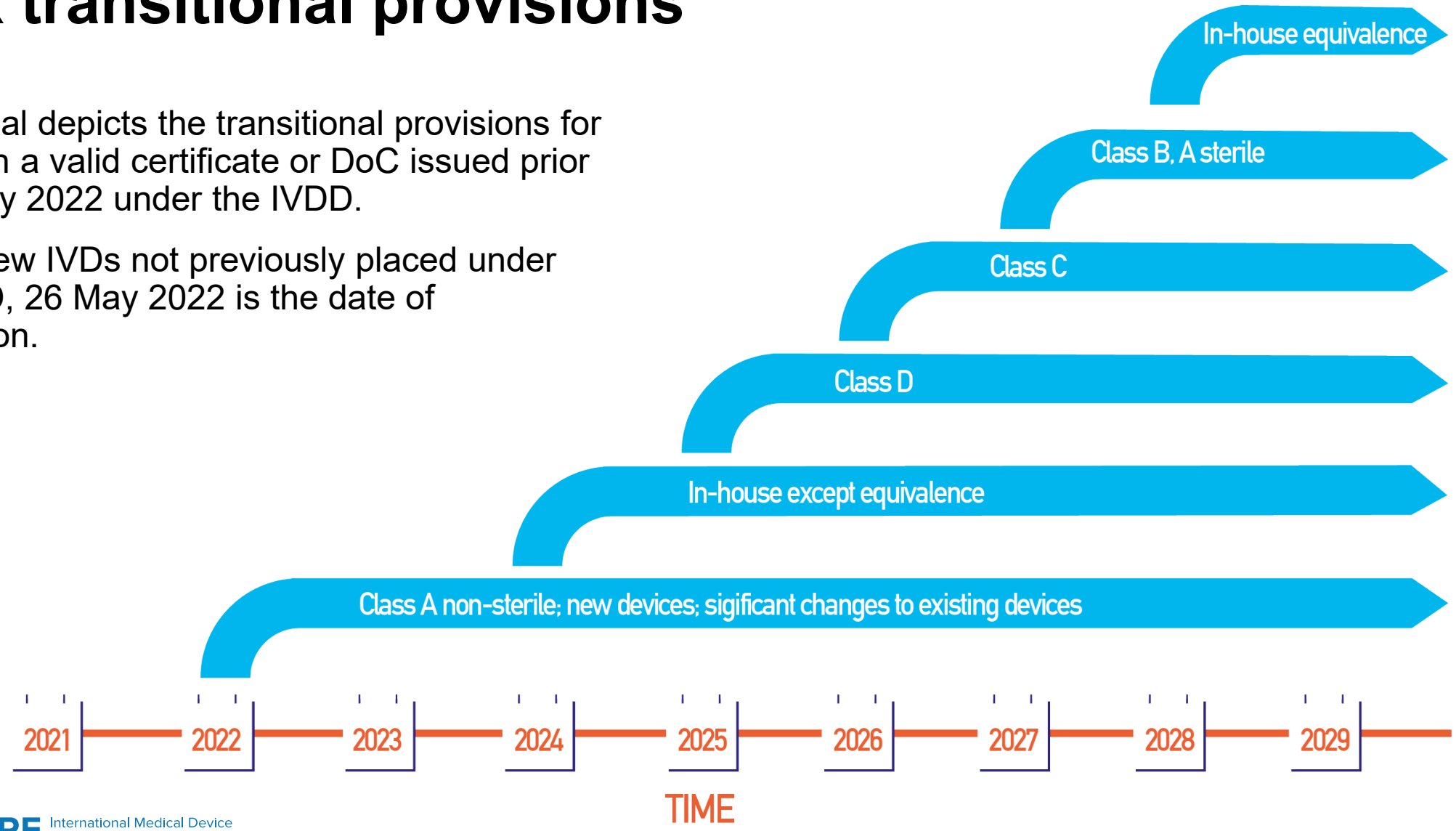
26 May All IVDD certificates become void 26 May

End of IVDR transitional period 26 May **2027**

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

July 2022
- ✓ 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)

August 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

+100 MDCG guidance documents to support all actors, including manufacturers and notified bodies

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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 notified body (NB) certificate under Directive 98/79/EC and requiring NB assessment under Regulation (EU) 2017/746 (Directive 98/79/EC Annex II List A and B; self-tests) - extend transition period by 1 year until 26 May 2025
- 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)