

GLOBAL STANDARDS, LOCAL IMPACT: INSIGHTS FROM THE EU MDR/IVDR FOR AFRICAN REGULATORS AND INDUSTRY

CLARE BIRMINGHAM
MEDTECH EUROPE



About MedTech Europe



MedTech Europe

from diagnosis to cure



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**170+ multinational
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*medical devices, diagnostics and digital health

**50 medical technology
associations**

**The European trade association for the medical technology industry including
diagnostics, medical devices and digital health.**

EU regulatory framework: state of play

- Regulation (EU) **2017/745** on medical devices (**MDR**)
 - applicable since **26 May 2021**, plus extra transitional period for ‘legacy devices’
- Regulation (EU) **2017/746** on *in vitro* diagnostic medical devices (**IVDR**)
 - applicable since **26 May 2022**, plus extra transitional period for ‘legacy devices’



Official Journal of the European Union

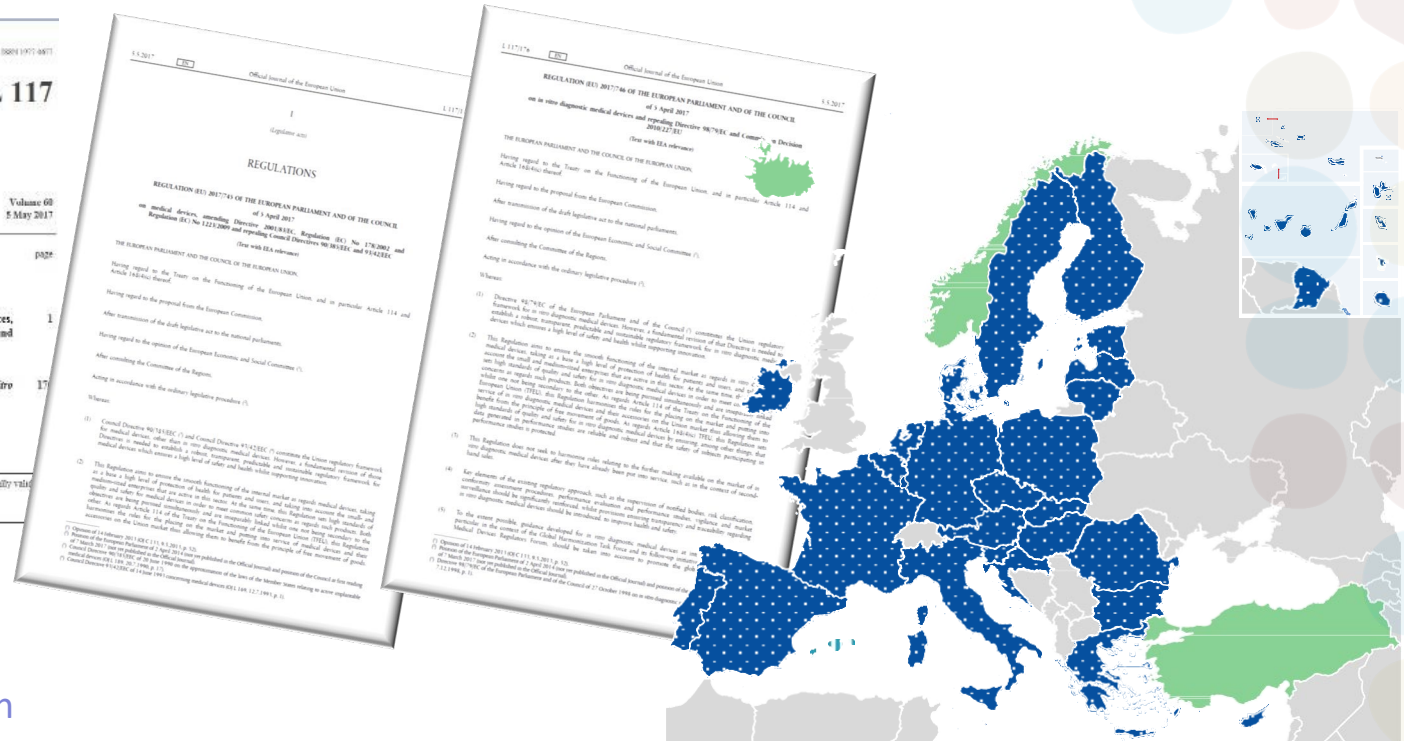
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Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC ⁽¹⁾

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU ⁽²⁾



Revision proposal

Expect same structure with some fundamental changes

- No proposed text available yet
- Commission's guiding objectives: Simplify / reduce administrative burden, support competitiveness and focus on device availability and patient safety

Innovation should get easier, e.g.,:

- Dedicated pathways for special devices types
- Improved procedures for running studies
- Early clarity on clinical expectations

Less burden, more predictability, e.g.,:

- Reduce duplication in reporting
- More digital tools
- Improved scientific coordination
- Mechanisms to rely on existing device approvals from outside EU

EU MDR/IVDR impact on international registrations

What's Changing

Updates to **CE-marking documentation** and **Certificates of Free Sale**

More **regulatory information and evidence** required under EU MDR/IVDR

Extent of change **varies by product and risk class**

What's Not Changing

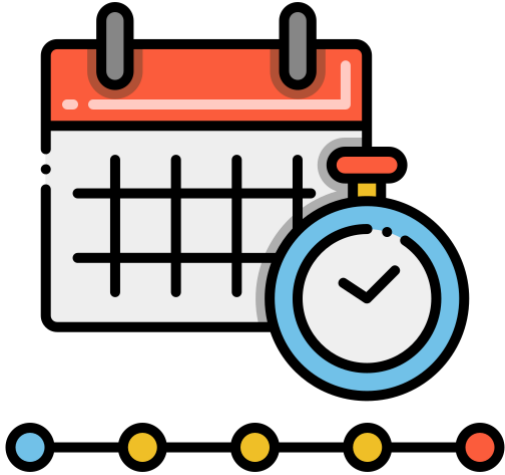
The **devices themselves** – same design, use, safety and performance

CE marking **continues to be accepted** in many countries outside Europe

CE marking remains a **trusted basis** for international registrations

Need for a transparent, predictable approach to manage changes arising from the transition to EU MDR/IVDR to avoid disruptions to product supply.

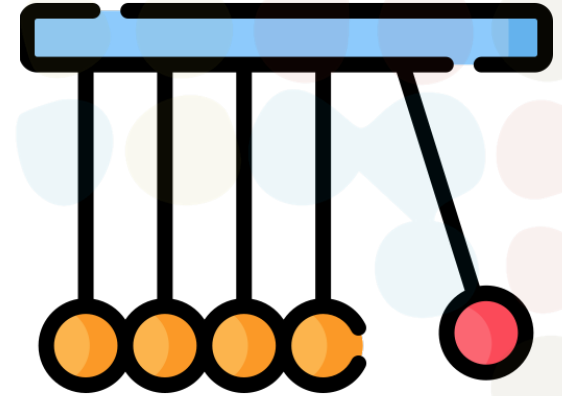
Challenges identified in the MEA region



Timelines



Documentation



Harmonization

- Unclear guidance on change management
 - Inconsistent documentation requirements
 - Limited harmonisation between authorities
- = Longer review timelines and risk of supply delays

Country Implementation Examples

Country	What they did	Lesson
Egypt & Bahrain	Required NB letters confirming CE validity	Strengthened traceability
Tunisia & UAE	Introduced grace periods for parallel selling	Prevented supply disruption
Kenya & Tanzania	Continued reliance on CE evidence with local vigilance	Balanced approach fit to capacity
South Africa	Transition from listing to risk-based classification	Stepwise capacity building

Opportunities & lessons learned for MEA

1. Plan phased transitions and clear grace periods
2. Consider guidance on how to deal with administrative changes arising from EU MDR/IVDR
3. Need for international harmonization and definitions for significant vs. non-significant changes
3. Practice reliance on trusted approvals such as CE-marking (EU MDR/EU IVDR)
4. Build regulatory capacity step by step
5. Strengthen regional cooperation



Applying a transparent, predictable approach

Acknowledge: Devices themselves haven't changed; only the EU documentation has

Accept: Updated EU MDR/IVDR certificates or formats without requiring full re-registration

Avoid: Duplicate testing or technical reviews when EU evidence already exists

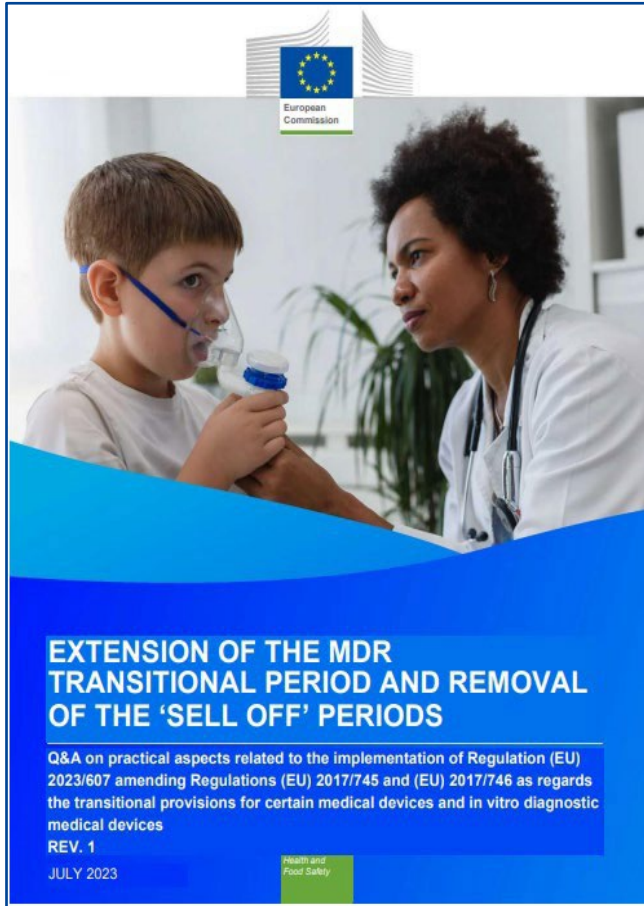
Advance: Continuity of supply while companies transition to new documentation

Align: National requirements with EU evidence standards to promote consistency

Assess: Monitor developments in the EU framework and their implications for local systems to stay up to date and adapt when needed.



European Commission ressources



European Commission

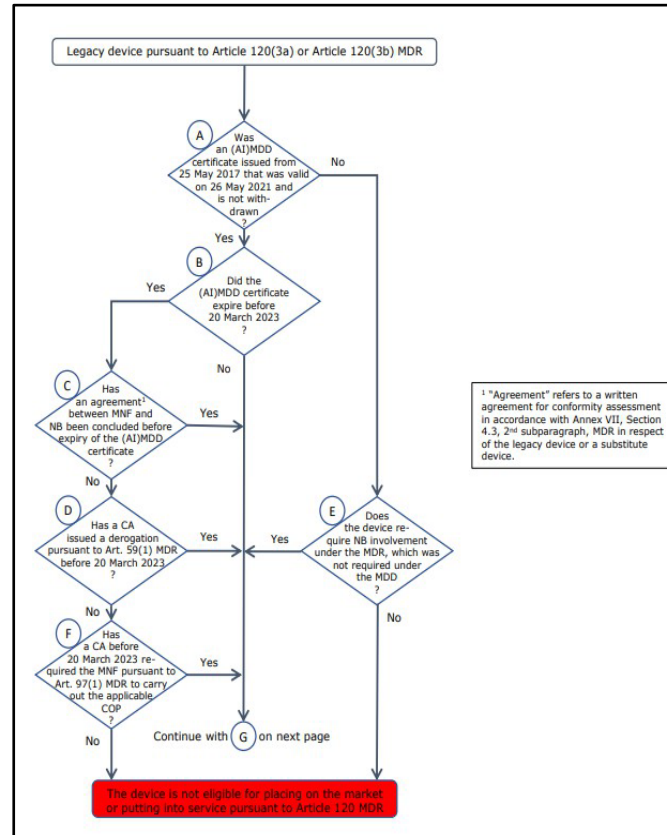
EXTENSION OF THE MDR TRANSITIONAL PERIOD AND REMOVAL OF THE 'SELL OFF' PERIODS

Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

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Health and Food Safety

[mdr_proposal_extension-q-n-a.pdf \(europa.eu\)](#)



[md_devices-art120_flowchart_0.pdf \(europa.eu\)](#)



European Commission

Factsheet for authorities in non-EU/EEA states on medical devices and in vitro diagnostic medical devices

This factsheet is for regulatory/competent authorities in countries that are not part of the EUEEA. For a general overview of the regulations please refer to the Medical Devices section on the [European Commission website](#).

In April 2017, the European Parliament and the Council adopted the Medical Devices Regulation (EU) 2017/745 (MDR) and the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR).

These two Regulations create a robust, transparent and sustainable regulatory framework, recognised internationally, which improves clinical safety and creates fair market access for manufacturers.

The MDR replaced the Medical Devices Directive 93/42/EEC (MDD) and the Active Implantable Medical Devices Directive 90/385/EEC (AIMDD). The MDR became applicable on **26 May 2021**.

The IVDR replaced the In Vitro Diagnostic Medical Devices Directive (98/79/EC) (IVDD). The IVDR became applicable on **26 May 2022**.

Both Regulations provide for additional transition periods, under certain conditions. The requirements enter into application gradually, starting with the provisions related to the designation of notified bodies and the ability of manufacturers to apply for certificates under the Regulations.

The MDR and the IVDR are directly applicable to all EU Member States and therefore create a level playing field across the EU market.

Manufacturers in third countries wishing to place devices on the EU market should familiarise themselves with the rules, timelines and obligations applicable under the Regulations. General information is available on the website of the European Commission, where there are also contact points for the national authorities for further enquiry into the application of the Regulations or for guidance. The European Commission also provides information on access to the EU market on its [Access2Markets](#) webpage.

As an authority in a third country that imports devices from the EU, you need to know about the timelines for implementing the Regulations. Please also bear in mind that during the transition periods, devices that are compliant with the previously applicable Directives and devices that are compliant with the current Regulations co-exist and may simultaneously be placed or made available on the EU market. This is of particular importance for those third countries that rely on the CE marking of devices to grant access to their markets.

To avoid disruptions in your market, health institutions, procurement bodies, customs officers and importers should be informed about the requirements and applicable timelines.

To avoid market disruption and allow a smooth transition from the Directives (AIMDD, MDD and IVDD) to the Regulations (MDR and IVDR), several transitional provisions are in place. Most devices with certificates or declarations of conformity issued under the Directives may continue to be placed on the market after the respective dates of application (Docks) of the two Regulations until the end of the relevant transition period. The exact timelines are further explained in this factsheet.

[MDR-IVDR_FS_third-countries_en \(europa.eu\)](#)



For more information or to further exchange, please contact:

Clare Birmingham, Manager International Affairs, MedTech Europe
c.birmingham@medtecheurope.org

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