For A Healthier Africa
AFRiSUMMIT
2nd - 5th November 2025
Hilton Grand Nile Hotel, Cairo - Egypt

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

CLARE BIRMINGHAM
MEDTECH EUROPE

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About MedTech Europe

MedTech Europe

from diagnosis to cure

OUR MEMBERS

170+ multinational corporations*

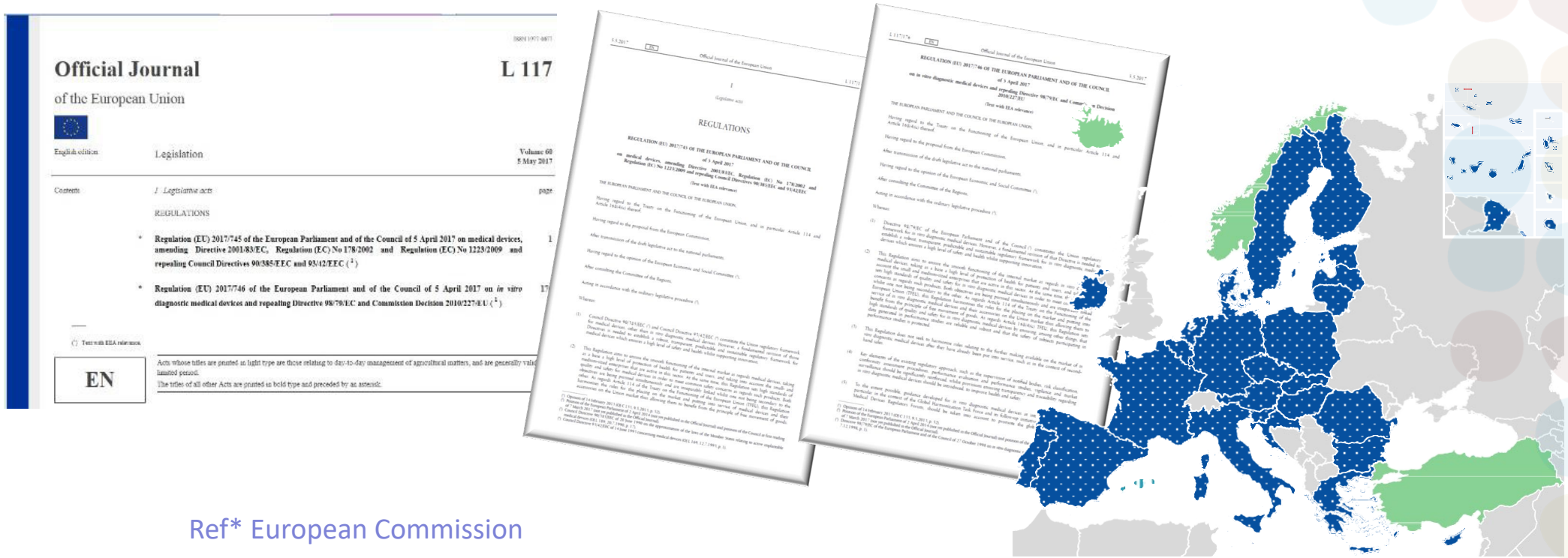
*medical devices, diagnostics and digital health

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‘



Ref* European Commission

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

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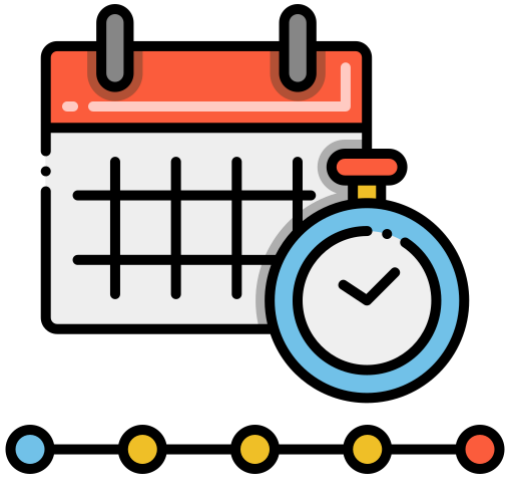
EU MDR/IVDR impact on international registrations

What's Changing	What's Not Changing
Updates to **CE-marking documentation** and **Certificates of Free Sale**	The **devices themselves** – same design, use, safety and performance
More **regulatory information and evidence** required under EU MDR/IVDR	CE marking **continues to be accepted** in many countries outside Europe
Extent of change **varies by product and risk class**	CE marking remains a **trusted basis** for international registrations

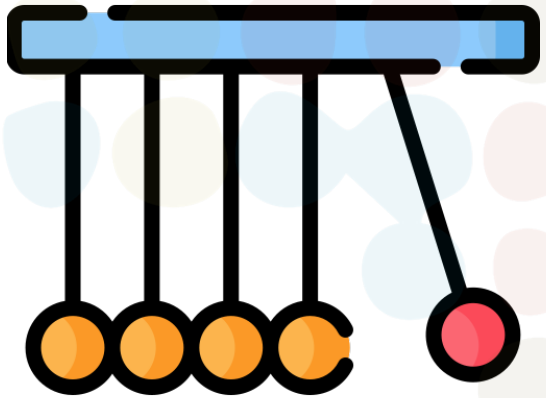
Need for a transparent, predictable approach to manage changes arising from the transition to EU MDR/IVDR to avoid disruptions to product supply.

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

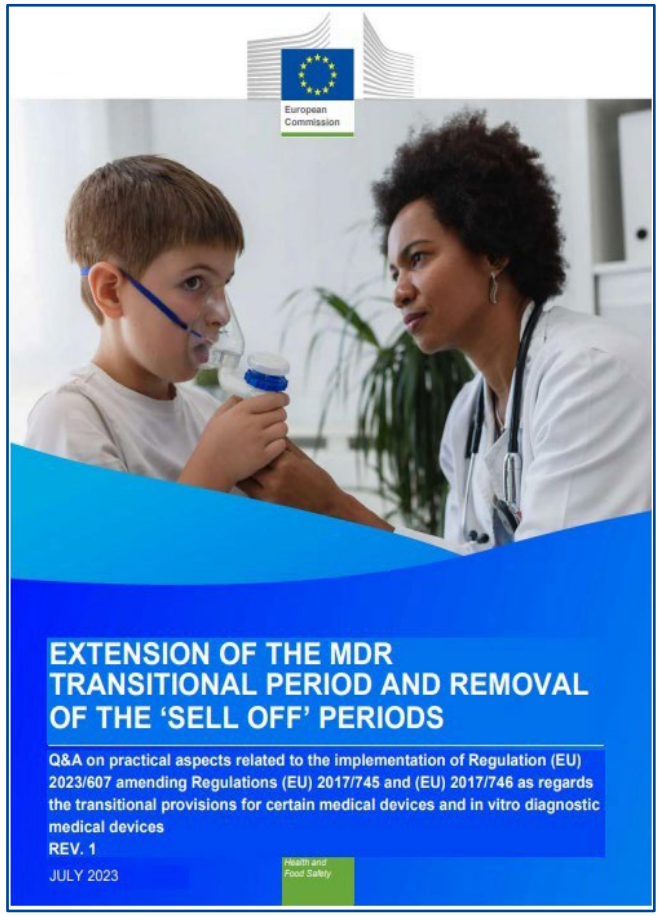
Avoid: Duplicate testing or technical reviews when EU evidence already exists

Advance: Continuity of supply while companies transition to new documentation

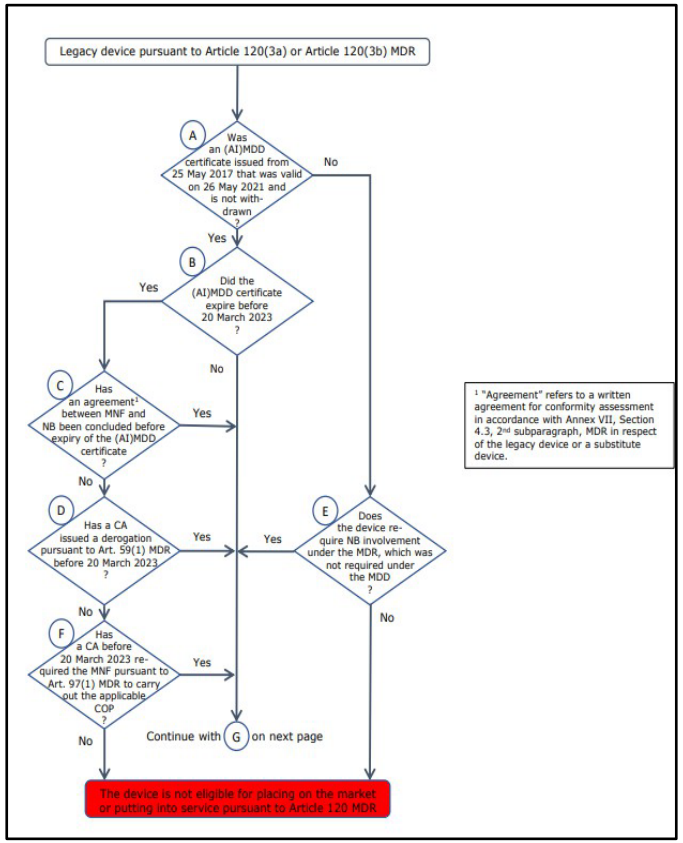
Align: National requirements with EU evidence standards to promote consistency

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



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



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

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

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THANK YOU