



# Medical Devices European Regulations

**Why is it worth it ?**

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# Summary

1. Reason #1
2. Reason #2
3. Reason #3
4. 2025 EU commission works
  - a) **Short term adjustments**
  - b) **Long term modifications**
5. Key takeaways

# Introduction

- **Israel is globally recognized for medical innovations. Many breakthrough technologies originate here.**
- **But innovation alone is not enough. Market access, regulatory credibility, and structured compliance determine whether that innovation becomes a global commercial success.**
- **That is where CE MARKING under the European Medical Devices Regulation becomes strategic.**
- **Since its first release, the EU REGULATIONS and particularly MDR was perceived as a significant administrative and financial burden, particularly by SMEs and startups, due to increased requirements for clinical evidence, higher costs, and limited notified body capacity,**

# REASON #1

## CE MARK remains THE GOLD STANDARD

### — Market access & competitive advantage

CE mark opens doors:

- EU market access – one of the world’s largest MD markets
- Faster expansion into other global regions - Many countries reference or accept EU MDR compliance
- Competitive differentiation & Regulatory Trust : compliant products are preferred in tenders and by distributors. The CE mark symbolizes strict regulatory compliance, safety, and high-quality clinical evidence recognized worldwide.
- CE certification simplifies regulatory reviews in many countries, reducing approval barriers and shortening commercialization timelines → less work per market and harmonized evidence generation.

### — Streamlined regulatory framework:

Clarity , harmonized standards – defined conformity assessment procedures – Robust quality management expectations.

→ Helps manufacturers plan product lifesciences with fewer surprises.

### — Stronger Post- Market Surveillance

Structured PMS (PMCF) – vigilance reporting – trend reporting

→ reduces risk of expensive recalls , liability claims and reputation damage.

### — Reimbursement

Many health systems and insurers require documented safety and clinical evidence – favor MDR-compliant devices

→ CE marking becomes a key of reimbursement and wider adoption.



# REASON #2

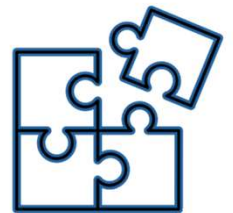
## BACK ON TRACK & HARMONIZATION

### — Better equipped against the resource constraints:

- For the Notified Body : targeted profiles, engaged qualification or extension of qualification and readiness of the manpower at all stages of the certification process
- For the Manufacturer: gaining experience with first(s) NB interactions, conformity assessment expectations.

### — Harmonization toward Reliance

- INTERNATIONAL COOPERATION : activities aiming at global regulatory convergence and international cooperation, such as the International Medical Device Regulators Forum (IMDRF) and the Medical Device Single Audit Programme (MDSAP).
- Outlook 2025–2026 EU & MDSAP ?
  - In 2025, the EU has observed the MDSAP Audits + the Auditing Organization surveillance audits
  - Ongoing work in connection with the MDCG 2020-14. Mapping MDSAP-MDR/IVDR.
- NB are most of the time AO, audits are conducted on the basis of ISO 13485.
  - Previous satisfactory experience of the transition from CMDCAS to MDSAP
  - Solid QMS with a mature level to adjust to any additional regulatory requirements.
- EU MDR compared to MDSAP will require a robust clinical data, as does TGA and or HC .
- MEDTECH supporting EU to join the MDSAP as member



# REASON #3

## DESTIGMATIZATION AND REPOSITIONING

### From MDR killed innovation → To MDR channeling innovation

- Enhanced Regulatory Clarity: EU REGULATIONS texts provide clear guidance on certification timelines, costs, and re-certification processes under MDR and IVDR.
- Impact on Compliance Planning: Manufacturers gain predictability in resource allocation and face stronger demands for clinical evidence and quality management.
- Proactive Manufacturer Engagement: Early, high-quality submissions and strong compliance histories are crucial to secure timely reviews from Notified Bodies.
- Strategic Business Integration: Integrating EU regulatory strategy into business planning enhances competitiveness and aligns with global standards.

### How ? Practicalities from the legislator

- Short-term “delegation act regarding annex VII”
- Long-term “EU MDR future amendment”



# 2025 EU commission works

## Short-term adjustments

### Implementing/Delegated Acts & Guidance

**Annex VII**  
(Requirements for NBs)

WET list

Breakthrough  
guidance

eIFU

(...)



Either already applicable or **expected in 2026**

## Long-term changes

### Amending Regulation

**MDR**

**IVDR**



Ordinary legislative procedure:  
**2 years or longer for enactment**  
**Earliest applicability: 2028**

# Short-term adjustments

## Implementing act – “Annex VII”

### Aims

#### Quotations

- Enhance the reliability of estimated cost of the overall requested services  
Further exchanges of complete information necessary for application, content of offers,...

#### Timelines

- Improve the predictable timelines for conformity assessment while accounting for device complexity and risk  
Maximum timelines, clock-stop system, ...

#### Monitoring of cost & timelines

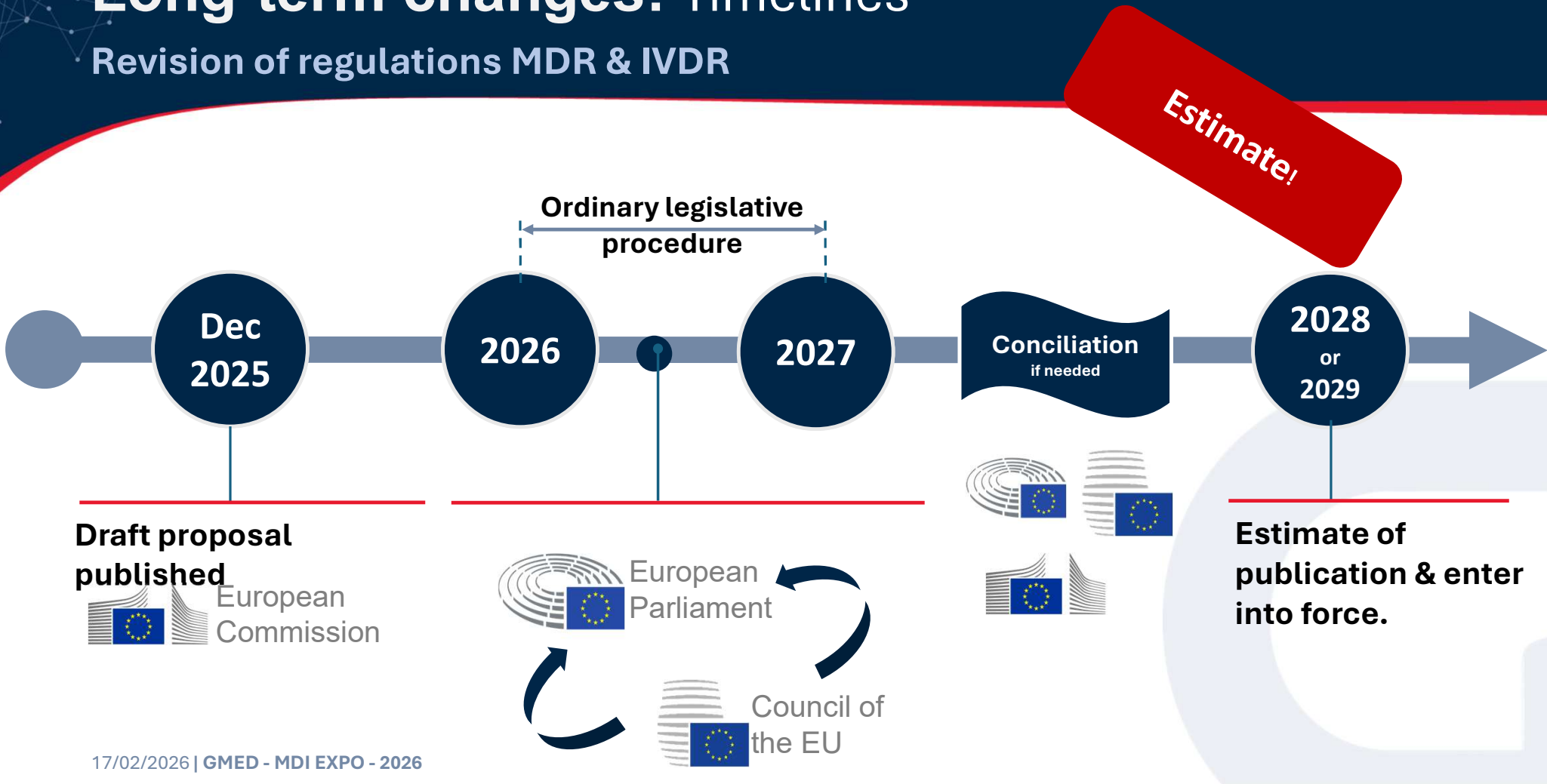
- KPIs to be handled and published

#### RE-certification

- Harmonization of the processes for product certificates & QMS certificates  
Clarification of what has to be done & timelines..

# Long-term changes: Timelines

## Revision of regulations MDR & IVDR



# Long-term changes

Revision of regulations MDR & IVDR, Proposal of December 16<sup>th</sup>, 2025

## — SIMPLIFICATION AND PROPORTIONALITY (examples)

- PRRC - Removal of the detailed qualification requirements
- Removal of maximum period of validity of certificates. Instead of recertifying devices, notified bodies will carry out periodic reviews proportionate to the risk of the device
- Clinical data : more flexible for reliance on clinical data for equivalent devices, openness to expanded kind of clinical data,...
- WET : introduction of a definition instead of a list,

## — REDUCTION OF ADMINISTRATIVE BURDEN (examples)

- SS(C)P: scope of devices reduced to those devices for which the notified body must conduct a technical documentation assessment.
- PSUR: reduction of the updating frequency
- Reporting timeline for certain serious incidents
- Changes after certification: distinction between QMS & products changes + between changes without prior notification, prior approval or only after approval

# Long-term changes

Revision of regulations MDR & IVDR, Proposal of December 16<sup>th</sup>, 2025

- **INNOVATION AND AVAILABILITY OF DEVICES FOR SPECIAL PATIENT GROUPS OR SITUATIONS (examples)**
  - Conformity assessment procedures for breakthrough devices or orphan devices
  - Interruption or discontinuation of supply of certain devices
  - Derogations for public health emergencies, disasters or crises
  - ‘Grandfathering’ of legacy orphan devices
  
- **PREDICTABILITY AND COST-EFFICIENCY OF CERTIFICATION (examples)**
  - Structured dialogue
  - Reduction of involvement of NBs in conformity assessment of lower and medium risk devices
  - Scope of CECP reduced to class III implantable devices, + Commission to add other types of devices by delegated act.
  - Reduction of NB fees for micro & small manufacturers and orphan devices

# Long-term changes

## Revision of regulations MDR & IVDR, Proposal of December 16<sup>th</sup>, 2025

- **COORDINATION WITHIN DECENTRALISED SYSTEM (examples)**
  - Streamline process for regulatory status and classification of devices
  - Designation and monitoring of notified bodies
  - Dispute resolution mechanism between manufacturers and notified bodies (CA= 'ombudsperson' role)
  - Enhanced role of external expertise available to the regulatory system
  - Support from the EMA: scientific, technical and administrative support for the coordination among national competent authorities in areas, such as borderline and classification, multi-country clinical studies, derogations, vigilance and market surveillance. EMA will also provide support to SMEs
  
- **FURTHER DIGITALISATION (examples)**
  - Digitalisation of compliance tools (e-IFU, EU declaration of conformity)
  - Possibility to draw up documentation in digital format,
  - ...
  
- **INTERNATION COOPERATION (examples)**
  - activities aiming at global regulatory convergence and international cooperation, such as the International Medical Device Regulators Forum (IMDRF) and the Medical Device Single Audit Programme (MDSAP).
  
- **INTERPLAY WITH OTHER UNION LEGISLATION**
  - Combined studies involving medicinal products, medical devices and/or IVDs
  - Cybersecurity
  - Amendments to (EU) 2024/1689 on artificial intelligence

# Key Takeaway

## CE MARKING under EU REGULATIONS not merely a regulatory obligation

- EU REGULATIONS have matured, the amendments and adjustments have and will stabilize timelines, predictability and bring fundamental changes to process and requirements
  - Notified bodies' capacity has increased.
  - The system is operational and those who engage strategically NOW gain competitive advantage
- The question is not whether to comply ; the question is how early and how to approach compliance strategically and proactively**
- A commercial passport to EUROPE, attractive Medtech Market
  - A signal of credibility
  - A value enhancer
  - A risk management framework
  - A strategic growth enabler

***CE: From Access by Default  
to Access by Design***

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