MedTech Europe
from diagnosis to cure

MDR implementation – State of Play

MedTech Europe's perspective

22 January 2025

Orthopaedic Surgical Manufacturers Association (OSMA) Winter Meeting

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About MedTech Europe

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

MedTech Europe
from diagnosis to cure

OUR MEMBERS

145+ multinational corporations*

50 medical technology associations

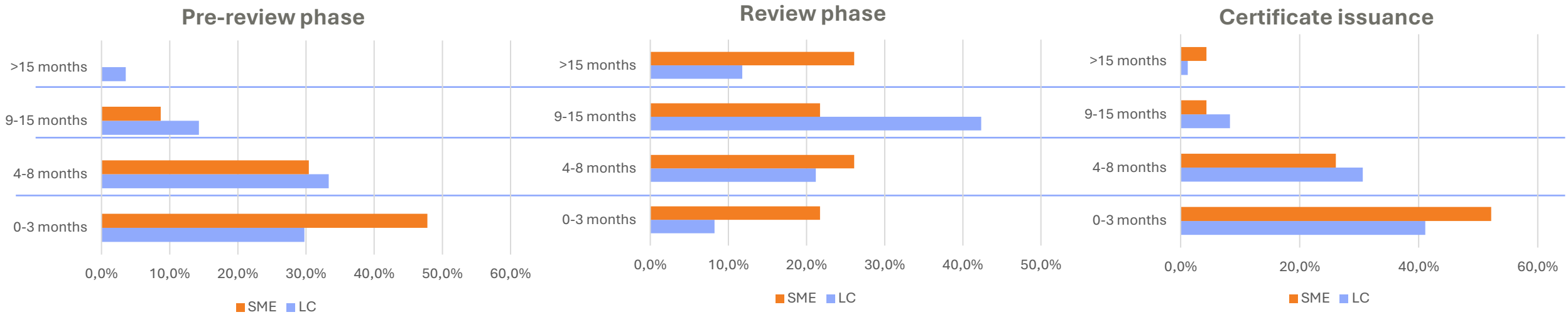
*medical devices, diagnostics and digital health

Timelines

EU QMS certification under MDR

(Total responses: 88)

MedTech Europe survey (link)



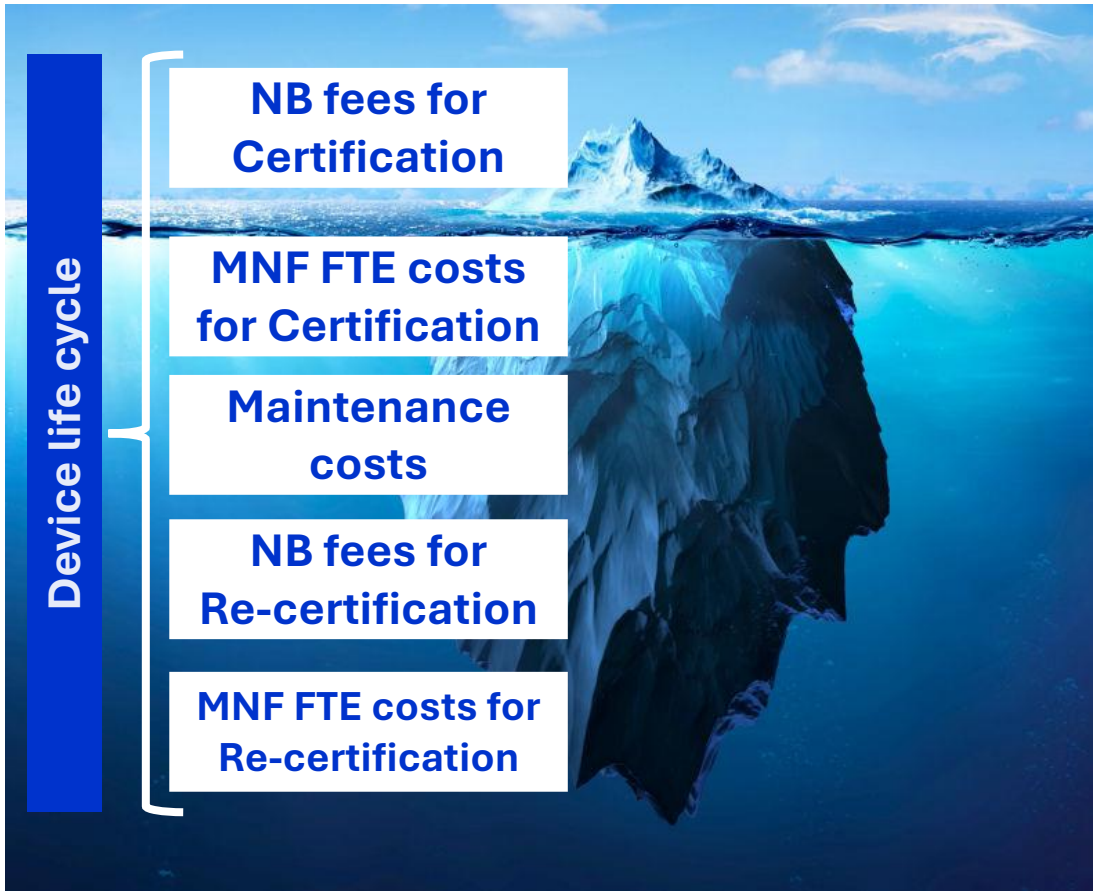
- EU QMS certification: average completion time **~19.5 months**
- **Little difference** between SMEs and large companies regarding timelines.

Phase	Percentage of total time
Pre-Review	**28%**
Review	49%
Issuance	**23%**

51%

Regulatory Costs to obtain & maintain IVDR/MDR certification throughout the device life-cycle

MedTech Europe survey (link)



- **NB fees for certification increased ~100% for QMS & for TD assessment certification**.
  - Delays and time needed for certification are significant contributors
- **Many additional costs need to be accounted for apart from NB certification fees,** including:
  - Manufacturer's FTE costs to complete certification
  - Maintenance costs that are needed to maintain the certificates (e.g. the fees for PMS reports, vigilance and annual NB surveillance)
  - Manufacturer's FTE costs to maintain certification
  - NB fees for re-certification after the 5-years period

Regulatory Costs: Overview of *average* costs to obtain & maintain MDR certification throughout device life-cycle

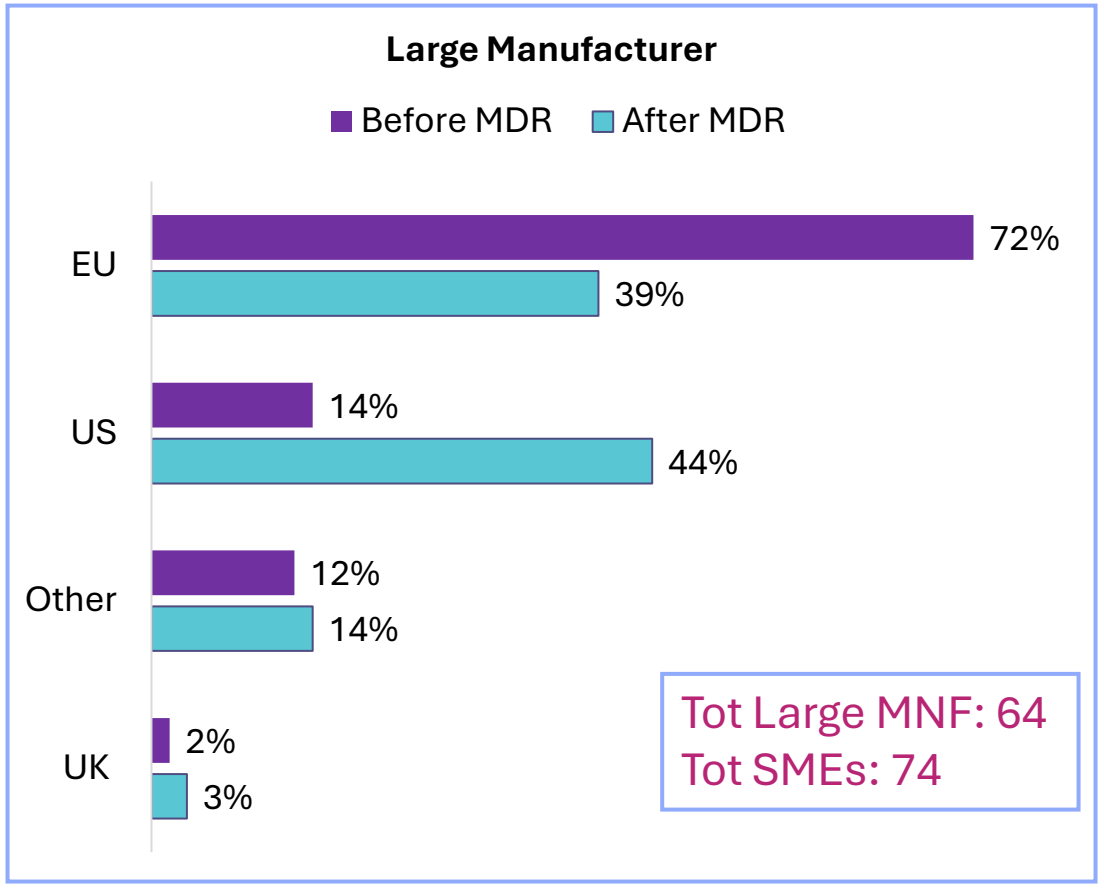
MedTech Europe survey (link)

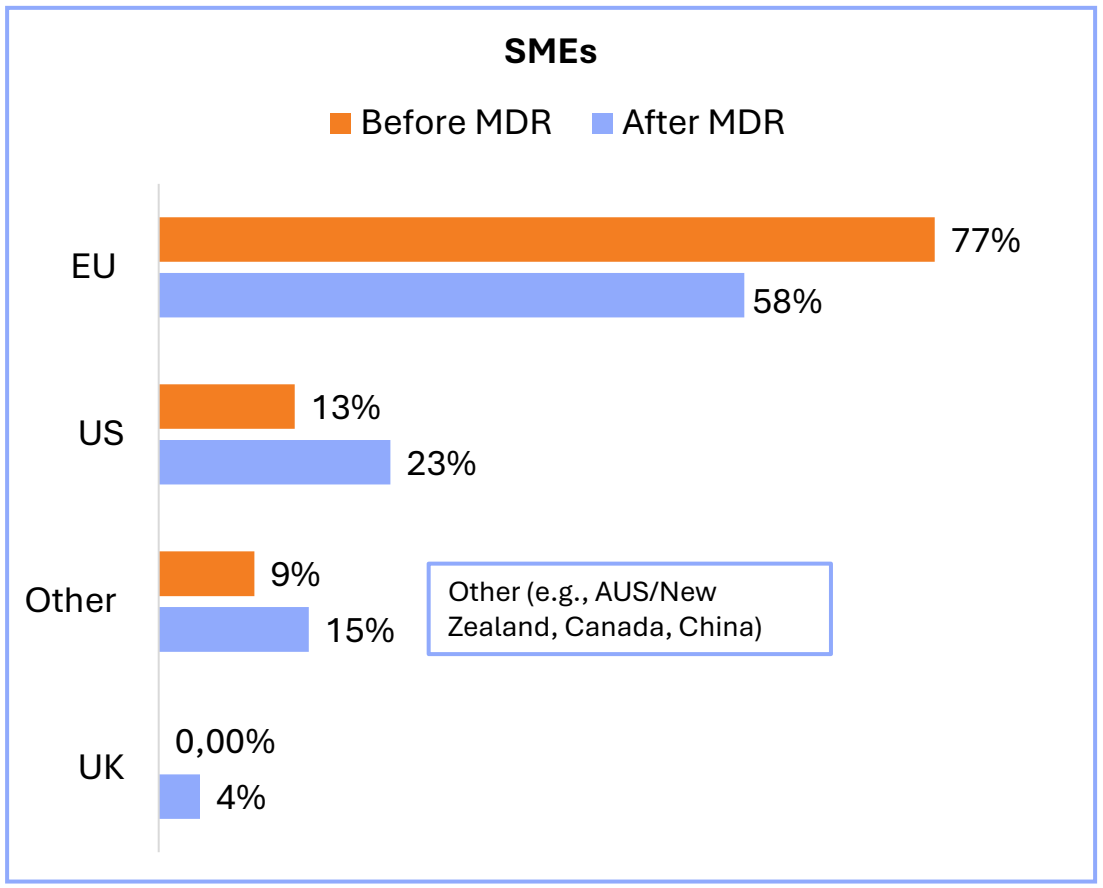
	QMS	Technical documentation assessment
Certification	NB fees for cert. ~**136,981 €** Manufacturer's FTE costs ~**490,525 €**	NB costs for cert. ~**176,202 €** Manufacturer's FTE costs ~**3,445,738 €**
Maintenance	Yearly maintenance costs for ALL classes subject to NB cert. ~ **99,648 €** Maintenance costs accumulated after 5-years ~ **498,242 €**	
Re-certification	**Limited data** at the present time – MedTech Europe ongoing efforts to gather more data	

Note: large variability in figures

Innovation Launch: Preferred geography before and after MDR Date of Application

MedTech Europe survey (link)





MDR dramatically affects the choice of the EU as the main option for a first regulatory approval by large manufacturers and SMEs, with a **reduction of 33% and 19% respectively**.
On the contrary, the choice of **other geographies increased significantly**, especially the **US.**

Timeline for future reform of IVD and MD Regulations

European Commission Targeted Evaluation of IVDR/MDR

Q3 2024 – Q4 2025

Shorter-term output → **Ongoing: Support fixes of regulatory system using tools of IVDR/MDR** *(eg: Implementing / Delegated Acts)*

Mid to longer-term output → **From 2026: expected to lead to European Commission legislative proposal**

- **Call for Evidence: Targeted Evaluation of IVDR/MDR –** open consultation until 21 March 2025
- **2nd Manufacturer survey on IVDR/MDR implementation:** started end-2024, runs until 28 February (link)

Political process could last years

Three pillars of MedTech Europe Call to Action & Activities

1 **(Technical) Fixes within current IVDR/MDR**

Short-term

Specific technical measures that can be addressed by MDCG via existing tools*

2 **Targeted measures with legal weight**

Short-term

4 urgent ‚bridging' measures that support device availability, innovation and competitiveness

3 **(Systemic) Legislative Reform of IVDR/MDR**

From 2026

Legislative proposals that realise our vision regarding **efficiency, innovation & governance**

* e.g. IA/DA, guidance, pilot programs

EU industry welcomes and supports the Targeted Evaluation
A full legal proposal could take years…
We need different actions in the short-term

1

Support fixes of regulatory system through guidance and other tools

1. **Deliver on the goals of MDCG 2022-14** (structured dialogue, leveraging evidence, reduce tech doc. sampling burden…)
2. **Enabling electronic Instructions for Use (e-IFU)** for all medical technologies
3. **Promote global convergence** of regulations, specifically via Medical Device Single Audit Program (**MDSAP**) initiative
4. **Other topics**: EUDAMED, Clinical aspects, …

2

Urgent bridging measures with 'legal weight'

1. **Bring predictability** to **timelines & costs** in technical documentation assessment and change control
2. **Introduce accelerated pathway** for breakthrough **innovation**
3. **Adapt certification** to follow a life-cycle approach (**renewals**)

Additionally, a **package of legislative reforms** with input from the Targeted Evaluation

3

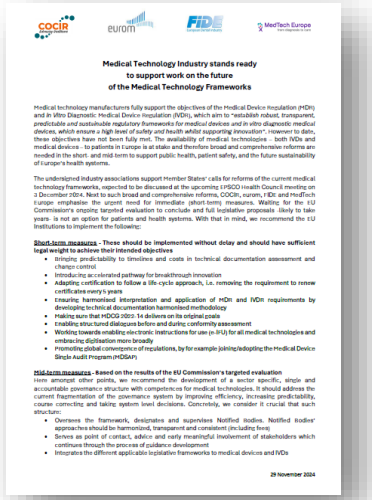
- Dramatically **enhance efficiency** and robustly increase Europe's **attractiveness for innovation** in medical technologies
- To underpin the above, **a single, dedicated governance structure** should be established which oversees and manages the regulatory system

MedTech Europe's Vision for the Future of our Regulatory System (see paper)

Towards the December 2024 EPSCO (Health Ministers) meeting

MTE Position Paper
(Nov 2023)

Open Letter to EU COM undersigned by NAs
(Oct 2024)



Pre-EPSCO Joint Industry statement
(Nov 2024)

MedTech Europe Survey report 2024
(Dec 2024)

MTE advocacy toolkit

Internal use:

- Narrative
- Q&A to support narrative

External use

- Slide deck to explain narrative

&

Many papers / surveys developed at National level

Ministers of Health Meeting: Outcome

Joint French-German paper, endorsed by 9 Member States in total on, e.g., :

1. **Reduced administrative burdens** in IVDR and MDR
2. **Centralisation role** for the **European Medicines Agency** (EMA)
3. **Predictability** of assessment timelines
4. **Pathways** for innovation

IVDR/MDR was an open AOB item (link to recording)

Views of the other 18 Member States *vary,* e.g., regarding the role of **EMA…**

Overall conclusion: Debate needs to continue and intensify!

- **Strong consensus**: EU Commission needs to deliver reforms
- **European Commission** recognizes challenges, will step up its work, both short term and after targeted evaluation
- **Lack of consensus on**: Timeline for reform & Which changes are necessary

IVDR/MDR Reform: Firmly on the EU Political Agenda!

- **EU Commission:** Mission letter to new Health Commissioner calls out IVDR/MDR
- **EU Parliament:** Joint Resolution on urgent need to revise the IVDR/MDR
- **EU27 Member States:** Joint papers and EPSCO debate on need for IVDR/MDR reforms
- **Healthcare Professionals:** BioMedical Alliance papers and conference panels
- **Patients:** European Patient Forum papers
- **Notified Bodies:** Team-NB (NB association) papers and conference panels

IVDR/MDR Reform: Political Landscape and Timing

European Industry	**EU Commission**	**EU Parliament**	**EU Council**
Deliver certain (urgent) measures now with legal weight ***System reforms supported by Targeted Evaluation***	**Deliver certain measures in 2025 – limited areas (e.g. 6 Implementing /Delegated Acts)** but will **await Targeted Evaluation for any broader system reforms**	**Strong support for reforms** including **immediate measures**	**Many countries support reforms; cautious support for immediate measures** **Majority wants to wait for Targeted Evaluation**
Asking for: 1. ***Short term:*** a) ***Use 'existing tools' to deliver**: e-IFU, single audit program, etc.* b) ***4 immediate 'bridging' measures** to bring predictability and support innovation* 2. ***Mid-term:*** ***Full legislative reforms** to deliver on efficiency, innovation and governance*	Conducting Targeted Evaluation of IVDR/MDR to end-2025 Health Commissioner 2024-2029 priorities Mission letter include (Sept '24) : • Implementation • Possible legislative reform • Support for device availability • Support competitiveness of medtech	Joint resolution for shorter- and longer-term reforms of IVDR/MDR (Oct' 2024) *"Calls on the Commission to propose, **by end 1Q 2025**, delegated and implementing acts to the MDR and the IVDR to address the most pressing challenges and bottlenecks"* MEP Peter Liese (June '24) detailed proposal for amending the MDR	Statement from Competent Authorities/Heads of Medicines Agencies 3 December EPSCO Ministers of Health meeting: 15 countries in favour of reforms

KEY QUESTIONS: WHAT and WHEN ?

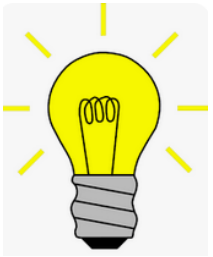
IVDR/MDR: Targeted evaluation of IVDR and MDR

Deadline:
21 March 2025

Call for evidence

Particular focus will be put on SMEs involvement

Questionnaire-based public consultation



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Consultation with particular stakeholder's groups, including workshops

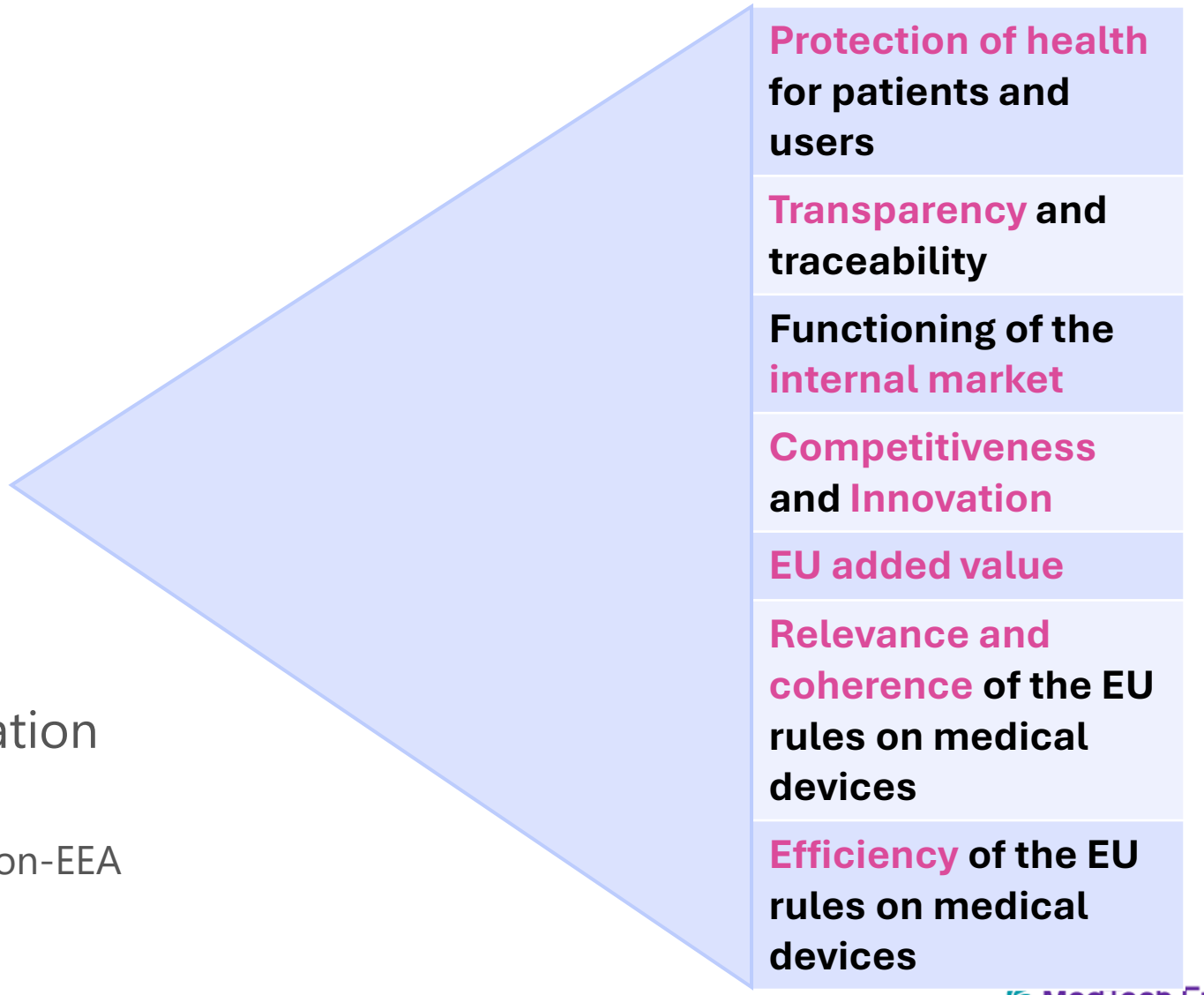
Consultations with the Medical Device Coordination Group

	Questionnaire-based public consultation	Call for evidence
Aim	The objective of the public consultation is to collect evidence and data **from relevant stakeholders** for the Commission to **take stock and assess** whether the rules: • are **effective, efficient and proportionate** • are **relevant:** meet current and emerging needs • are **coherent:** align with other actions • have **EU added value** Assess the **performance** of the legislation.	This **call for evidence** is **open** for feedback. **Calls for evidence are more open, information-seeking exercises, which can go on to inform the direction or shape of a policy.** A Call for evidence **describes the problem to be tackled and objectives to be met, explains why EU action is needed**, outlines policy options and describes the main features of the consultation strategy, including whether a public consultation with a questionnaire is needed.
Free text input	5000 characters in Q8: Additional information 5000 characters in each **"Please specify"** text boxes	4000 characters
Additional submission	File attachment less than 5 MB Only files of the type pdf,txt,doc,docx,odt,rtf are allowed	File attachment less than 5 MB Only files of the type pdf,txt,doc,docx,odt,rtf are allowed
Link	Questionnaire	Give your feedback

Questionnaire-based public consultation – Main chapters

- Q2: Admin data
- **Q5: MD section**
- **Q6: IVD section**
- Q8: Additional information

Q3 for citizens, Q7 for non-EU/non-EEA Public Authorities



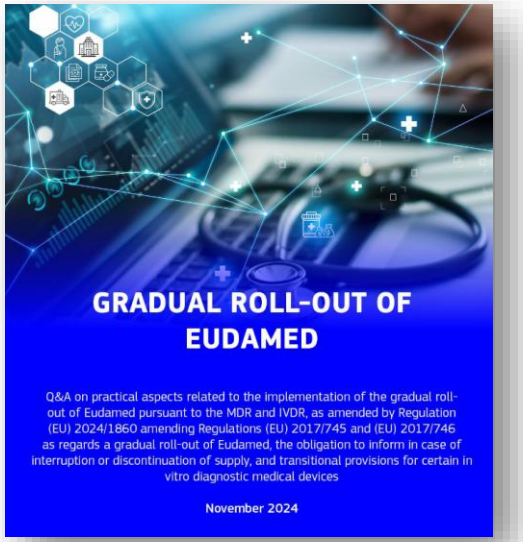
Implementing and Delegated acts in 2025

EU Commission initiative*	Scope	Planned for adoption	Experts involved
Delegated regulation	To **group devices with clear clinical similarities** under the same identifier: 'Master UDI-DI'; e.g. spectacle frames, lenses and ready-made reading glasses (unique identifiers)	by **Q1 2025**	**MDCG**
Implementing regulation	To allow **electronic instructions for use** for all medical devices intended exclusively for use by health care professionals	**by Q2 2025**	**MDCG**
Implementing decision	To establish an additional expert panel for **orphan and pediatric devices**	by **Q2 2025**	
Delegated regulation	To **expand the list of well-established technologies** (WET) under the MDR to exempt them from certain legal requirements and reduce administrative burden	**Q3 2025**	**MDCG**
Implementing regulation	To **reclassify** certain **well-established technologies**, for which the application of the general classification rules in Annex VIII of MDR is not proportionate to the devices' nature and respective (limited) risks	**Q4 2025**	**Comitology**
Implementing regulation	To set uniform rules for **Notified Body requirements** under the MDR and IVDR	**Q4 2025**	**Comitology**

**Note: Draft texts are not available so far*

EUDAMED gradual roll-out

Source: EUDAMED roadmap published at the European Commission's website (July 2024)



The European Commission published a supporting Q&A to explain the transition periods of the various modules for mandatory use (more on Regulation (EU) 2024/1860 here)

Resource tool for implementation:

EUDAMED information centre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POSITION PAPER

Smooth transition to the mandatory use of EUDAMED

Perspectives from manufacturers

2 December 2024

MedTech Europe published a position paper reflecting on the **preparation needed to ensure a smooth transitioning to the mandatory use of EUDAMED modules**. Ahead of the foreseen confirmation of several EUDAMED modules as functional in 2025, MedTech Europe asks for **increased accessibility, consistency and efficiency** of the central database for medical devices through technical and regulatory means. The position paper provides a summary of the **measures needed to mitigate the burden and to prepare users for transitioning to mandatory use of EUDAMED.**

July 2025

OJEU notice Actor, UDID, CERT

Jan 2026

Mandatory use Actor, UDID, CERT

July 2026

Transition for UDID registration ends

VGL module launch & mandatory use

Jan 2027

Transition for CERT registration ends

TRAINING

Recent Guidance published by Medical Device Coordination Group

Article 10a – interruption or discontinuation of supply	Q&A rev.1 Q&A Obligation to inform in case of interruption or discontinuation of supply	Dec 2024
	MDCG 2024-16 Manufacturer Information Form on Interruption or Discontinuation of Supply of certain medical devices and certain in vitro diagnostic medical devices	Dec 2024
	MDCG 2024-16 Annex Device Identification table	
EUDAMED	Q&A on practical aspects related to the implementation of the gradual roll-out of Eudamed	Nov 2024
PMS and Vigilance	MDCG 2023-3 rev.1 Questions and Answers on vigilance terms and concepts as outlined in MDR/IVDR	Nov 2024
Unique Device Identifier (UDI)	MDCG 2024-14 Guidance on the implementation of the Master UDI-DI solution for contact lenses	Nov 2024
Clinical investigation	MDCG 2024-15 Guidance on the publication of the clinical investigation reports and their summaries in the absence of EUDAMED	Nov 2024
Borderline and Classification	MDCG 2024-13 Regulatory status of ethylene oxide (EtO) intended for the sterilisation of medical devices	Oct 2024
	MDCG 2022-5 rev.1 Guidance on borderline between medical devices and medicinal products under MDR	Oct 2024
Notified bodies	MDCG 2024-12 Corrective and preventive action (CAPA) plan assessment: guidance and templates for conformity assessment bodies, notified bodies, designating authorities, and joint assessment teams	Oct 2024
	MDCG 2024-12 Annex I Form Template CAPA plan and assessment thereon	
	MDCG 2024-12 Annex II Form Template JAT review of the CAPA and the DA's opinion	
	MDCG 2019-13 rev.1 Guidance on sampling of devices for the assessment of the technical documentation	Dec 2024
Legacy devices	MDCG 2021-25 rev.1 Application of MDR requirements to "legacy devices" and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC	Oct 2024

IVDR/MDR Article 10a
Prior notice of supply interruptions

Entry into force 10 Jan 2025

- **Obligation to notify 6 months in advance** if it is reasonably foreseeable that a supply interruption or device discontinuation results in (risk of) serious harm to patients or public health
- **Recently published documents** after many workshops with Regulators
  - EU Commission guidance (Q&A)
  - Manufacturer Information Form (MDCG 2024-16)
  - Device Identification Table
- **Still many points to be clarified -** Competent Authorities' mitigating measures? Penalties? Confidentiality? National rules superseded by EU system ? Etc

Responsibility for risk assessment falls on manufacturers

Manufacturers need to develop a process and implement it in their QMS

More recent updates and Next steps

- **MedTech Europe Webinar (18 December 2024)**: MDR/IVDR Article 10a Unfolded
  - Informative panel session – recording available to MedTech Europe members with a detailed explanation of new obligations

- **What's Next?**
  - Draft European Commission decision tree to guide manufacturers in assessing when and how to report potential supply issues

- **MedTech Europe gathers practical experience with implementation of Art 10a**

  Please reach out to us !

(Foreseen) Timemlines for IVDR/MDR reforms …

2024

- New Parliament & Commission
- Implementing IVDR & MDR
- Political attention for IVDR/MDR reform

2025

- Implementing IVDR & MDR (incl. IA/DAs)
- Targeted Evaluation
- Surveys (GÖG)
- Preparation of legislative reform

2026

- Potential legislative proposals
- Potential start of Negotiations in Council and Parliament (political phase)

*IA/DA: Implementing /Delegated Acts

Importance to keep up the momentum!

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Thank you

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