MedTech Europe
from diagnosis to cure

MedTech Europe's note for members

Call for Evidence

For European Commission's Public Consultation on EU rules on medical devices and *in vitro* diagnostics – targeted revision

24/09/2025

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Call for Evidence for European Commission's Public Consultation on EU rules on medical devices and in vitro diagnostics – targeted revision

Aim of the consultation

The European Commission has launched a Call for Evidence to support a **targeted reform** of EU rules on medical devices and *in vitro* diagnostic medical devices (IVD). The aim of the consultation is *to "simplify and streamline the regulatory framework, and make it more cost-efficient and proportionate, while preserving a high level of public health and patient safety and maintaining the overall structure of the current regulatory framework."*

Purpose of this document

This is an additional opportunity for our sector to shape the future of the EU medical technology regulatory framework; therefore **we encourage members to participate**.

MedTech Europe provides you with this note to help in developing your own contribution: it contains **bullet-point guidance** under each goal stated in the consultation and references to **published advocacy documents** where available.
This practical approach is intended to encourage broad participation while ensuring broad alignment across the sector.

Practical aspects

Submission details

- **Link:** the Call for Evidence consultation is available at the European Commission's website
- **Timeline:** The consultation runs from 9 September to **6 October 2025 midnight** (Brussels time).
- **Format:** Each contribution may include up to **4,000 characters in free text** plus **one attachment** of 5 MB (supporting evidence, position paper, or case examples).
- **Please note that you cannot include links in the free-text field box**, only in the attached 5 MB document.
- Please note that your submitted information will appear **publicly** on the consultation website. The name of the individual submitter can be opted to be anonymised, but the name of your organisation will always appear.

How you can contribute

We strongly encourage all members to submit your own perspectives, while taking into account our shared advocacy goals. Submissions that reflect your organisation's experiences and priorities will carry a stronger message and significantly enhance the credibility and representativeness of the sector's overall input.
There are multiple ways to structure your input: the outline below is provided only as one suggested approach, you may choose to use selected parts.
Where relevant, you will also find links to existing position papers for further background and detail.

Important disclaimer

Please refrain from any copy-pasting from MedTech Europe materials. They are provided solely as inspiration and as a reminder of our shared goals. The European Commission likely will identify and remove duplicative submissions as being 'campaign entries'.

Confidential information

Companies may choose to share confidential or sensitive information. If you decide to submit such information, for example, via the European Commission's designated email address sante-med-dev@ec.europa.eu, please note that MedTech Europe is not involved in this process and bears no responsibility for how the information is handled, used, or protected. Such contribution will inform the Commission's evaluation process and ultimately fed into its evaluation report on the Targeted Evaluation. The European Commission has informed us that when they receive information by email:

- Confidential information will be handled with restricted access on a need-to-know basis within the Medical Devices Unit, with appropriate marking features and access rights limitations applied to ensure confidentiality.
- Manufacturers are encouraged to specify in the cover message accompanying their submission the purpose of transmitting such data (e.g., targeted reform of MDR/IVDR) and the specific uses they consent to.
- Under specific circumstances, access may be granted to other EU bodies, such as the European Anti-Fraud Office, the European Public Prosecutor's Office, and the European Court of Auditors.
- The Commission is subject to transparency obligations under EU law, specifically Article 4(2) of Regulation (EC) No 1049/2011, which governs access to documents. In accordance with this Regulation, access to documents may be requested, and the Commission will assess each request on a case-by-case basis, considering the protection of commercial interests.

Guidance for inspiration on providing feedback for the Call for Evidence

General introduction could state your organisation's overall position on the IVDR (*In Vitro* Diagnostic Medical Device Regulation) and MDR (Medical Device Regulation).

You could express your support for an MDR/IVDR revision proposal which:

enhances competitiveness; ensures the regulatory system is efficient, lean and fit-for purpose; supports innovation; is well-governed; and ensures devices are available for patients and health systems, etc.

Note that it is important – since it may take time for the revision proposal to be published – that industry supports short term measures to be adopted in the immediate term.

For further contribution, one way to structure your input could be **around the goals 1-7 as listed in the Call for Evidence** – see in the below table.

For example, you can **list your organisation's top 3 issues with case examples, or simply make concrete suggestions to achieve the below goals**.

MedTech Europe provides you with a non-exhaustive list of suggestions under each of these goals. Please note that MedTech Europe also has several proposals for how the revision proposal could solve key issues, for example in our paper on the Future Regulatory System or our Report on Administrative Burden.

For further background and inspiration, we invite you to consult MedTech Europe's dedicated **webpage on the future of EU Medical Technology Regulatory System**.

1. Reducing the administrative burden, including reporting obligations

See: MedTech Europe report on Administrative Burden under IVDR and MDR

Here the respondent could discuss the need for the revision proposal to address specific areas, for example:

- The requirements for conducting clinical investigations / performance studies should be made more efficient and risk-proportionate
- Notified Body conformity assessment should be streamlined; eliminate mandatory recertification.
- Duplication in post-market surveillance reporting should be eliminated, and reporting requirements should be made more risk-proportionate
  See: MedTech Europe position paper on Submission of vigilance reports to Notified Bodies under EU MDR & IVDR
- EUDAMED and nomenclature systems should be made more usable by reducing data entry duplication, harmonizing existing databases and coding practices.
  See: MedTech Europe position paper on Smooth transition to the mandatory use of EUDAMED
- Economic operators' roles should be clarified to prevent unnecessary repetition of tasks.
- More digitalization is needed in the system, from standardised digital documentation submissions to electronic instructions for use and digital labelling.
- Routine blood draws should be exempted from requirement to apply for performance study authorisation – link to discussion paper

Or the respondent could speak more generally about what the increased administrative burden under the regulations vs. the directives, has meant for your organisation, your products and the patients you serve.

2. Enhancing the predictability and cost-efficiency of the certification processes of notified bodies

Here the respondent could discuss the need to address specific points and provide solutions, for example:

- How to enhance the life-cycle assessment of products
- Address the lack of transparency regarding the cost and the scope of services as well as conformity assessment timeline
- Clear definition of substantial change: any modification that could adversely impact
  - the **safety or performance** of a medical device
  - the device's **intended purpose** or its prescribed conditions for use
  - the manufacturer's **Quality Management System (QMS)** compliance with the legislative requirements

3. Making conformity assessment requirements more proportionate, especially for low- and medium-risk devices and those serving special patient needs

Here the respondent could discuss (provide examples and case studies where possible):

- Better predictability and timelines for assessments
- Proportional oversight and requirements for legacy devices; and or
- The need for accelerated and holistic pathway for special devices types meeting unmet patient needs: orphan devices, pediatric devices, breakthrough innovations
- Simplified conformity assessment for low- and medium-risk devices (avoid "one-size-fits-all" approach)
- Address Notified Body bottlenecks with proportional oversight and resource allocation
- Introduce fast-track reviews for low-risk and well-established technologies
- Tailored clinical evidence requirements based on risk classification and device history
  Clearer guidance for use of real-world evidence and literature data

4. Enabling further digitalisation

Here the respondent could advocate for:

- eIFU for certain MD lay use devices where the layuser receives information from their healthcare professional and the device is frequently used
  See: MedTech Europe position paper on Electronic Instructions for use (eIFU) for certain medical devices intended for lay users; Coming: eIFU for IVD near-patient testing

- Digital label providing non-essential information (e.g. Importer or Authorised Representative contact details)
- Digitalisation of the Technical Documentation – See: MedTech Europe position paper

5. Streamlining procedures, including those on governance

Here the respondent could mention key tasks and responsibilities to be centralised and reshaped under a new single structure:

See: Joint discussion paper on the future governance of medical technologies in Europe

- Notified Body oversight & harmonisation
- Promote alignment internationally & within EU legislation
- Appeal possibility & resolution of disputes
- Guidance development & harmonised application
- Stakeholder engagement
- Innovation & Competitiveness
- Accountability
- Better support for SMEs
- Enable early dialogue between manufacturers and notified body (e.g. on clinical evidence)
  See: Joint Paper on clinical strategy as part of pre-submission dialogue between manufacturer and Notified Body

6. Enabling the EU medical device sector to benefit from international cooperation (including reliance, where appropriate)

Here the respondent could shape its input around

- Value of EU joining Medical Devices Single Audit Program and recognising MDSAP certificates for CE marking – link to joint reflection paper
- In the interest of supporting EU competitiveness, a strong need for allocating resources dedicated to international regulatory cooperation to enhance trust in CE marking – growing trend in lack of recognition and reliance on CE marking
- Mutual Recognition Agreement with Switzerland – link to joint statement
- Data sharing agreement and access to EUDAMED for MHRA, to enable indefinite recognition of CE marking in the UK
- International reliance for special device types (orphan, pediatric, breakthrough)
- Adopt model / uniform Certificate of Free Sale to enhance reliance on CE marking – some countries not recognising CFS issued by certain EU countries (e.g., Finland)

7. Better aligning the regulatory framework with other relevant legislation

Here the respondent should consider which areas most impact your products and where alignment is most needed. Some suggestions for areas are provided below:

- Digital & Data Legislation
  - Artificial Intelligence (AI) Act, European Health Data Space Regulation (EHDS), Data Act
    See: MedTech Europe position paper on simplification of EU digital legislation
  - Heath Technology Assessment (HTA) Regulation
  - General Data Protection Regulation (GDPR): Align MDR/IVDR with GDPR by clarifying lawful bases for processing personal data in clinical investigations, performance studies and post-market surveillance.
- Green and sustainability legislation including REACH, packaging and packaging waste, etc.
- Liability & Consumer Protection Framework
  - Product Liability Directive (PLD)/Representative Actions Directive (RAD): Clarify how MDR/IVDR confidentiality and PMSV reporting rules interact with new procedural rules of PLD/RAD to ensure a fair, predictable legal environment that fosters innovation.
  - General Product Safety Regulation (GPSR): clarify its applicability to medical devices, especially in relation to online marketplaces.

8. You may also wish to highlight any topic important for you that **is not explicitly mentioned** in the background to the Call for Evidence, such as innovation pathways, change notification processes.

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.
www.medtecheurope.org.

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