# European Commission's Targeted Evaluation of the IVDR & MDR

# Explanatory Note for Members to Support Contributions to the ongoing Public Consultations

*Disclaimer: This Explanatory Note is intended to support MedTech Europe members and the corporate members of our national association members in responding to the European Commission's Targeted Evaluation of MDR and IVDR. It is provided for informational purposes only and does not constitute legal or regulatory advice. While MedTech Europe has used its best efforts to ensure the accuracy and relevance of the information provided herein, we cannot guarantee its completeness or correctness. MedTech Europe accepts no legal responsibility for the use of this guidance, and companies should seek their own legal or professional advice before making any decisions based on its content. MedTech Europe reserves the right to change or amend this document at any time without notice in order to keep the information up to date.*

## Table of Contents



## I. Purpose of this document

- This document is meant to **encourage MedTech Europe members** (corporate members and national associations) **to respond to the two Public Consultations** that are part of the 'Targeted Evaluation' of the European Commission and assess the appropriateness of the EU IVD and MD Regulations.
- The consultations will be **decisive in determining whether and how the IVDR and MDR will be further developed.**
- This Explanatory Note is meant to provide assistance for easier handling of the Public Consultations. The outline below is intended as a support and recommendation only. This explanatory note focuses on the questions that require material and supporting information from the members.
- **The deadline for submission is 21 March 2025** for both Public Consultations.

## II. The Targeted Evaluation

- The 'Targeted Evaluation' is an important initiative by the European Commission to assess the EU Regulations (EU) 2017/746 (IVDR) and (EU) 2017/745 (MDR) for *In Vitro* Diagnostic Medical Devices and

Medical Devices. It aims at **determining whether the current rules are *effective, efficient and proportionate***, *meet current and emerging needs, align with other EU actions, and have EU added value*.

- The ongoing **two Public Consultations are an essential part of the 'Targeted Evaluation'**, complemented by further surveys and workshops and leading to a final assessment report scheduled for Q4/2025.
- **It is important that the Commission receives a significant range of input** from the various national markets and individual companies to get a comprehensive picture about the impact of the current rules on device availability, innovation-capacity, costs, admin burden and competitiveness of the sector.
- **MedTech Europe will also provide its own response.** It will follow the line of numerous previous submissions to the EU institutions regarding the severe challenges with the current IVDR and MDR Regulations and the urgent need for an EU CE marking system which is efficient, innovation-friendly, and well-governed (MedTech Europe The Future of Europe's Medical Technology Regulations and MedTech Europe 2024 Regulatory Survey: key findings and insights).

## III. Practical Aspects

- The two Public Consultations are of different nature:
  - **A Questionnaire-based consultation** – it includes 38 core questions with 85-90 sub-questions to gather structured input (see Part IV of this document);
  - **A Call for Evidence** – allows for free-text feedback, needs and suggestions (see Part V of this document).
- **Scope:** Both Public Consultations cover IVDs and MDs.
- **Access:** Both consultations are accessible [here]. It needs registration with an email address.
- **Transparency:** All contributions will be published on the European Commission's website, including documents provided as annexes:
  - The free-text feedback to the Call for Evidence is automatically published upon receipt (here).
  - Responses to the Questionnaire-based consultation will be published by the Commission at the end of the consultation period, 21 March 2025.
- **Several submissions per company:** In general, organisations submit one common/consolidated response, unless the same organisation replies on behalf of different departments/categories of economic operators (i.e. SMEs versus large enterprises).
- For questions to MedTech Europe about the Targeted Evaluation, please email regulatory@medtecheurope.org.

*Confidential information:* As part of the European Commission's Targeted Evaluation of the MDR/IVDR, companies may choose to share confidential information. If you decide to submit such information via the 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**. This contribution will be used by the Commission to inform the evaluation process, ultimately contributing to the Commission's evaluation report on the Targeted Evaluation. The European Commission has informed us that:

- 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., evaluation 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.

**We strongly recommend that companies consult their legal counsels before sharing any commercially sensitive data.**
Please note that MedTech Europe has requested that the European Commission issue a communication for stakeholders, detailing how the data collected via the designated email address will be stored and processed. We will update this Explanatory Note should more information become available.

## IV. Structure of the Questionnaire-based Consultation

The Questionnaire-based consultation has eight Chapters:

### 1 - Introduction

Description and rationale of the Questionnaire-based consultation. Nothing to fill in.

### 2 - About You (Questions 2.1 – 2.19)

Information about the respondent to fill in.

*Important!* To have access to all questions related to manufacturers of medical devices select both:

- under Question 2.2 - Company/Business **and**
- under Question 2.3. - Economic Operator as per Art 2(35) MDR and Art 2(28) IVDR

*Important!* **Question 2.19 Contribution publication privacy settings.** The option 'anonymous' removes the name of the person responding to the questionnaire, but the name of the organisation, its transparency number, size, country of origin and the contribution will be published.

### 3 - Survey for Citizens

Not for manufacturers and other economic operators to fill in.

### 4 - Scope of the Questionnaire for Stakeholders

There is only one question, which is to determine whether you want to follow the questions for MDs (Part A / Chapter 5) or for IVDs (Part B / Chapter 6). You can also choose to respond to both parts.

| **5 - Questions on Medical Devices (MDR)** | **6 - Questions on In Vitro Diagnostic Medical Devices (IVDR)** |
|---|---|
| Both parts initially present 38 questions, organized into topical sections:<br>A. Protection of health for patients and users<br>B. Transparency and traceability<br>C. Functioning of the internal market<br>D. Competitiveness and Innovation<br>E. EU added value<br>F. Relevance and coherence of EU rules on medical devices<br>G. Efficiency of EU rules on medical devices | |

*Important!*
Some questions will trigger follow-up (dependent) questions in case you select **"disagree"** or **"strongly disagree."** These Sub-Questions provide additional context and allow for more detailed feedback through multiple-choice options and open Free Text field boxes (see Figure 1 below).

To maximize the impact of your responses, we encourage careful consideration of **disagree** or **strongly disagree** selections, as these unlock key opportunities for the European Commission to gather valuable insights. Engaging fully with these questions helps shape stronger feedback.
Note: all Free Text field boxes are 5000 characters each.

Considerations for responses to selected questions can be found in Annex I (for MDs) and Annex II (for IVDs) of this document.

### 7 - Additional questions for non-EU/non-EEA Public Authorities

This chapter does not appear for manufacturers and other economic operators.

### 8 - Additional information

Free Text Field for further comments (5000 characters) and opportunity to upload files (<5MB).

In Annexes I and II, MedTech Europe provides considerations for selected questions which members may take into account when preparing their own submission. The majority of questions selected are those where MedTech Europe plans to disagree or strongly disagree. The points for members to consider are highlighted to strengthen the industry response. Specific answers are not suggested and members may answer the questions as they wish. At the same time, members should avoid simply copy-pasting the points given for consideration. It is important that members highly adapt answers including providing specific examples and your experience in open-answer sections, as this should be especially valuable for making the feedback as impactful as possible.

Information on MedTech Europe's overall approach also is given for these questions.

## V. Second Consultation - Call for evidence (Free-Text Box)

### 1 - Format and approach

The Call for evidence provides a way to submit any evidence related to the implementation of the MDR and IVDR via two possibilities:

- Free Text Field of 4000 characters (please note that contribution therein becomes visible publicly immediately after submission)
- File attachments of less than 5 MB

To submit feedback under the ''Call for evidence'', click [here]. The deadline for contributing to the call for evidence is 21 March 2025.

### 2 - Considerations for members

The Call for evidence should be considered as an **additional opportunity for feedback** – rather than repeating the same information as submitted through the Questionnaire-based consultation. Members (companies and national associations) are encouraged to submit individually; and national associations may wish to ask your own corporate members to do the same. MedTech Europe plans to submit under the Call for Evidence, its 2024 Survey Report, the Report on Administrative Burden and other papers relevant for driving reform under the Targeted Evaluation.

The European Commission will be particularly looking for **concrete data (qualitative or quantitative) and examples on availability of devices, costs & benefits and potential solutions to the implementation challenges**.

- Companies should consider which **case studies and company data** they have available to share.
- National associations may wish to include here your relevant **position papers and national or local survey information** as well as other kinds of evidence.
- MedTech Europe encourages members to submit evidence where MedTech Europe currently has less data, including (but not limited to): your experience of recertification and change control.

# ANNEX I: Section 5 - Questions on Medical Devices (MDR)

## A. Protection of health for patients and users

**Question 5.3** MedTech Europe plans to strongly disagree with the option, "The sector and its industry is **duly regulated**," *Note: 'Duly' means 'in accordance with what is required or appropriate'*[1].

**Sub-Question 5.15**: Considerations for the Free Text Box (please address these or any other points you feel particularly strongly about): – give examples where this particularly impacted your company.

- **The risk-based classification is not risk-based** – the risk-based approach outlined in the MDR does not result in meaningful distinctions between lower-risk and higher-risk devices, creating challenges for products across all risk classes.
- **Lack of regulatory predictability and clarity –** The MDR has been implemented with evolving guidance, leading to uncertainty for manufacturers.
- **Limited capacity and availability of Notified Bodies** – capacity challenges with designated Notified Bodies have caused severe delays in conformity assessments, affecting market access for both existing and new devices.
- **Inflexible and disproportionate regulatory framework** – The current one-size-fits-all approach does not account for the specific needs of SMEs, breakthrough technologies, orphan devices, AI-driven innovations…
- **Barriers to timely innovation and market access –** The lengthy certification process, high costs, and complex administrative requirements have discouraged investment in innovative technologies, leading to manufacturer prioritising other markets over the EU.
- **Lack of effective derogation mechanisms for public health emergencies** – The EU-wide derogation mechanism (Article 54 IVDR / Article 59 MDR) has proven ineffective, with companies relying on national-level exemptions instead, leading to fragmented regulatory responses in times of crisis (example COVID-19).

**Question 5.17** MedTech Europe plans to strongly disagree that the extended transition periods of the Regulation have addressed the concerns our members had.

**Sub-Question 5.18**: Considerations for the Free Text Box (please address these or any other points you feel particularly strongly about):

- Considerable work has already gone into addressing short-term implementation challenges by the European Commission and other stakeholders. Legislators have given a total of two extensions to the

[1] See online dictionary, https://dictionary.cambridge.org/dictionary/english/duly

transition timelines, to ensure medical technologies remain available to patients; the common belief was that system readiness was lagging. Unfortunately, it has become clear that without addressing the core deficiencies, such extensions only postpone the impact.

- Another bottle neck of Notified Bodies capacity is already expected with the renewal of already issued MDR certificates (validity of 5 years).
- 'More implementation' alone will not be enough and improvements to address MDR systemic deficiencies are needed.

## B. Transparency and traceability

**Question 5.45** MedTech Europe plans to strongly disagree that the regulation has contributed to achieving:

- Transparency of information on devices in the EU
- Traceability of devices in the EU
- Trust in the regulatory system of medical devices

**Sub-Question 5.48** Transparency - Considerations for the Free Text Box (please address these or any other points you feel particularly strongly about):

- **Transparency Barrier:** EUDAMED is not fully functional, making it neither legally applicable nor fully populated. Public access to information remains limited.
- **Regulatory Interpretation Issues:** Unclear responsibility for uploading the Summary of Safety and Clinical Performance (Notified Body vs. manufacturer) and uncertainty about required content (e.g., patient section).
- **Impact of Delays:** Assess how postponed EUDAMED timelines have affected your project planning, budgeting, and IT resource allocation.
- **Testing Feedback:** If you participated in EUDAMED testing, evaluate whether your feedback was considered and if the system meets your needs in terms of efficiency and usability.
- **UDI/Device Submission Plan:** Ensure you have all necessary technical and regulatory information for a smooth transition. Challenges could include e.g., no correction function, burdensome manual processes, misaligned technical documents, and excessive data requirements beyond legal obligations (e.g., for unregistered devices, legacy devices, CIPS applications, and Manufacturer Incident Reporting forms).

**Sub-Question 5.49** Traceability - Considerations for the Free Text Box (please address these or any other points you feel particularly strongly about):

- **Traceability vs. Tracking:** Traceability identifies a device within the supply chain, a long-established practice by economic operators (batch/lot). The new requirement mandates hospitals to store UDI-DI/UDI-PI and include UDI-DI on implant cards and patient records. Due to tech limitations, users often request UDI data via alternative means, though manufacturers meet labeling requirements. However, bulk data downloads from EUDAMED remain unavailable for hospitals.
- **EUDAMED Constraints:** Barriers to traceability include inefficiencies in managing mergers/acquisitions (devices can't be transferred to a new legal entity) and rigid registration rules requiring a new UDI-DI for data errors or business events (e.g., Notified Body changes). This leads to unnecessary work, duplicate records, and risks during vigilance events.
- **Lack of Flexibility:** Unlike the FDA, there's no legal mechanism for exemptions or alternative approaches (e.g., regulatory discretion for certain devices). The method for ensuring non-sterile implants' traceability remains unclear.

**Sub-Question 5.51** Trust - Considerations for the Free Text Box (please address these or any other points you feel particularly strongly about). *Note: MedTech Europe understands the questions of trust as related to trust by other jurisdictions in the current regulatory system under MDR.*

---

- **Declining CE Marking Reliance:** Non-EU countries that once depended on CE marking are moving away, creating uncertainty about a device's lawful market status (e.g., Brazil no longer relies on CE marking).
- **Unrealistic Transition Timelines:** The Regulations' transition periods have been repeatedly amended due to the scale of required changes. Frequent MDCG guidance updates further undermine regulatory stability and trust.
- **Eroding Trust in the System:** MedTech Europe would respond "strongly disagree" if assessing healthcare professionals' and patients' trust in the current regulatory system. MDR's impact on device availability and innovation shifting away from Europe have weakened confidence.
- **Reduced Regulatory Trustworthiness:** The transition from the Directives to MDR has further diminished trust in the European regulatory framework.

## C. Functioning of the internal market

**Question 5.73** MedTech Europe plans to strongly disagree with:

- The rules being applied fairly and impartially to all stakeholders before a device is CE-marked,
- The rules being applied fairly and impartially to all stakeholders after a device is CE-marked,
- The creation of an equal playing field for all economic operators, regardless of company size or market position.

Members who plan to (strongly) disagree with the above questions should provide their own rationale and examples they have experienced, for the following Free Text Boxes:

**Sub-Question 5.74-75 Reasoning why BEFORE** (for example, some but not all Notified Bodies may provide structured dialogues, conduct of multi-country clinical investigations…)

**Sub-Question 5.76-77 Reasoning why AFTER** (for example, Notified Bodies may treat change notification process, PSUR or vigilance reviews differently…)

**Sub-Question 5.78-79 Reasoning why equal playing field** (for example, an SME company may have a more difficult time finding a Notified Body, some Member States have national distributor databases…)

**Question 5.86** MedTech Europe intends to disagree on the extent to which guidance documents produced by the Medical Device Coordination Group enhance legal clarity on the provisions of the Regulation.

*Important!* Note: disagreeing or strongly disagreeing does not open up sub questions and there is no Text Box to elaborate on these aspects here.

## D. Competitiveness and Innovation

**Question 5.87** MedTech Europe plans to strongly disagree with the contribution that the Regulation has made to the **competitiveness** of the medical device sector in the EU and **innovation** in the medical device sector taking place in the EU.

**Sub-Question 5.89 and Sub-Question.91** Considerations for the Free Text Box (please address these or any other points you feel particularly strongly about):

- The unpredictability, complexity, and burden of the regulations means that many devices on the market today as well as new, innovative medical technologies are not reaching patients in Europe as they should[2]. Add your own experience of how this is impacting your company.
- You may wish to comment on how you are experiencing the perspective of non-EU regulators (e.g. Brazil, UK and Australia) when they look at the value of CE-marking.
- The competitiveness of the wider industry and even the viability of many small businesses (SMEs) are at risk[3]. Lack of clarity on the new requirements and timelines by non-EU/non-EEA authorities which may lead to less trust and ultimately cause a barrier to competitiveness.

## E. EU added value

**Question 5.96** MedTech Europe plans to agree that it is preferable to have one EU Regulation in this field instead of individual national regulations covering the same aspects.

## F. Relevance and coherence of the EU rules on medical devices

**Question 5.97** MedTech Europe plans to strongly disagree with the Regulation addressing:

*Important!* Note: disagreeing or strongly disagreeing does not open up sub questions and there is no Text Box to elaborate on these aspects here.

- **Emerging health challenges and evolving patient needs.**

  Considerations for members: MDR Article 59 (EU-Level Derogations) has proven impractical. During the pandemic, manufacturers had to rely on national derogations, as the EU-wide mechanism was not activated [4]. The mechanism is not designed for rapid decision-making. There is no way to apply for derogations for groups of devices. The lack of an effective EU-wide emergency approval pathway means that in future health crises, manufacturers and patients cannot rely on a single, streamlined process to bring critical medical devices to market. Consider calling for an effective EU-wide emergency approval pathway.

- **Emerging technological (including digital) or scientific progress in the sector.**

  Considerations for members: The MDR's complex and costly pre-market regulatory requirements, combined with long certification timelines, delay the access of new technologies, including for example, digital health solutions, AI-driven devices, and next-generation implants. Many innovative products face longer time-to-market in the EU compared to other regions, putting Europe at a competitive disadvantage in global medical technology innovation. The current framework does not accommodate the iterative nature of AI, where algorithms improve over time, leading to regulatory uncertainty and hindering investment in digital health. The MDR does not include a streamlined and accelerated approval pathway for breakthrough or high-impact medical technologies. Other regions, such as the US (FDA's Breakthrough Devices Program), provide faster regulatory routes for innovative devices, making them more attractive markets for first launches.

---

[2] The MDR has dramatically affected 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. By contrast, the choice of other geographies increased significantly. Source: MedTech Europe 2024 IVDR & MDR Survey Report [link]

[3] For example,see survey report by the German Chamber of Commerce and Industry (DIHK), the MedicalMountains cluster initiative, and the German industry association SPECTARIS '*Current assessment of the German medical device manufacturers on the effects of the EU MDR*', December 2023: while the report did not address business closure specifically, the percentages of planned and reported discontinuations of devices are severe enough especially for smaller companies, to indicate that their business viability is at risk.

[4] In fact, this derogation has only ever been used once at EU level in 2023 – well after the pandemic was essentially over.

- **Potential future technological and scientific innovation in the sector (e.g., research and development)**
  Considerations for members: Similar points to the above may be considered. MDR, in its current form, does not include specific pathways and other measures to foster current and future technological and scientific innovation. Instead, its rigid and burdensome framework discourages investment in breakthrough, orphan, niche and other technologies which are essential for meeting the needs of today and tomorrow.

**Question 5.98** To what extent do you agree that the Regulation is coherent with other EU rules in the following fields:
*Important!* Note: disagreeing or strongly disagreeing does not open up sub questions and there is no Text Box to elaborate on these aspects here.

- **Digital Regulations:** MedTech Europe plans to "Disagree" on digital regulations that conflict with MDR/IVDR provisions, such as the AI Act's integration of pre- and post-market requirements, certification triggers, clinical/performance evaluation pathways, and notified body designation. The European Health Data Space also raises issues with the dual definition of a medical device as an Electronic Health Record (EHR) system, impacting cybersecurity requirements.

- **Cybersecurity:** MedTech Europe plans to "Agree" regarding the Network and Information Security Directive II (NIS2), which adopts an organizational cybersecurity approach rather than a product-specific one. This does not conflict with MDR. Additionally, manufacturers of digital medical devices are exempt from the Cyber Resilience Act, as MDR already includes a risk-based approach to product cybersecurity (per Annex I). This is recognized in Recital 25 of the Cyber Resilience Act, acknowledging the existing cybersecurity requirements under MDR and MDCG 2019-16 Rev.1 guidance.

**Question 5.99** Is there another field of coherence of the MDR with other EU rules on which you would like to comment on? If yes, please add them under Q5.100.
**Sub-Question 5.100** Considerations for the Free Text Box (please address these or any other points you feel particularly strongly about):

- Consider elaborating on the speed at which new EU rules are emerging; the impact for your company and your products (for example, impact of other EU rules on labelling, on conformity assessment under MDR …)
- Although this question refers to 'another field', in theory you may comment on any EU rules which you consider to be coherent or non-coherent with MDR
- EU rules which are not listed above under Q 5.98, include for example (not exhaustive): Product Liability, Batteries, Standardisation, Electro Magnetic Compatibility, Machinery, Blood, Blood Products and Blood Establishments (SOHO), Animal by Products, Electrical and Electronic Waste, Deforestation, Personal Data, VAT, Electronic Commerce, Late Payment, Imports from Third Countries, Trading of Goods, etc.

**Question 5.102** MedTech Europe plans to disagree that provisions in the Regulation are coherent with one another
**Sub-Question 5.103** Considerations for the Free Text Box (please address these or any other points you feel particularly strongly about):

- Consider where elements within the Regulation are confusing for you or seem to contradict basic principles.
- Illustrative examples only (please provide examples which you find important):

- For example: Preambles 1 and 2 state that one of the aims of the Regulation is to support innovation. But, there are no provisions for fostering innovation in the Articles
- Article 16 refers to importers, distributors and ''other persons'' in the heading but not in the article's text (the article text only mentions importers and distributors), which has caused enormous amount of confusion as to whether system and procedure pack producers (SPPP) are meant to be covered by article 16 or not.

## G. Efficiency of the EU rules on medical devices

MedTech Europe plans to strongly disagree with the following statements across all four phases, based on its experience over the past three years:

*Important!* Note: disagreeing or strongly disagreeing does not open up sub questions and there is no Text Box to elaborate on these aspects here.

- The costs of complying with MDR for the listed activities are reasonable.
- The administrative costs for the listed activities are acceptable.
- The costs of MDR compliance for the listed activities will decrease once the regulation is fully implemented.
- The administrative costs for the listed activities will decline once the regulation is fully in effect.

**Phase 1** **(Question 5.105):** activities related to generating evidence on the safety and performance of devices; activities related to clinical investigations; activities related to setting up quality management systems; activities for the designation of notified bodies under the Regulation

**Phase 2** **(Question 5.106):** activities concerning the initial certification of devices and the maintenance of certificates; activities concerning the first placing on the market or putting into service devices for which the conformity assessment does not involve a notified body; activities related to derogations to the conformity assessment

**Phase 3 (Question 5.107):** activities for the compliance with post market obligations; activities related to vigilance; activities related to market surveillance

**Phase 4 (Question 5.108):** activities for providing information on devices or certificates; activities providing guidance to the sector

## H. Additional information

**Question 8.1** Please feel free to include any additional relevant points that you feel important and that are NOT covered by the questionnaire itself. The free text field allows for 5000 characters including spaces.

MedTech Europe, as of this moment, plans to include points on recertification, governance and any explanations/clarifications of our answers to the particular parts of the questionnaire.

# ANNEX II: Section 6 - Questions on IVDs (IVDR)

## A. Protection of health for patients and users

**Question 6.3** MedTech Europe plans to strongly disagree with the option, "The sector and its industry is **duly regulated**," *Note: 'Duly' means 'in accordance with what is required or appropriate'*[5].

**Sub-Question 6.15**: Considerations for the Free Text Box (please address these or any other points you feel particularly strongly about): give examples where this particularly impacted your company.

- **Risk-Based Classification Issues:** The risk-based approach in the Regulations fails to create meaningful distinctions between lower- and higher-risk devices, leading to challenges across all risk classes and disproportionately affecting manufacturers of lower-risk products.
- **IVDR's Overreach:** IVDR expands Notified Body oversight to ~78% of IVDs, compared to ~8% under the IVD Directive. This approach mirrors MDR but disregards the actual risk posed by the IVD, applying a one-size-fits-all regulatory burden to many low-risk tests, such as [insert example], that previously did not require oversight.
- **Notified Body Capacity Issues:** The limited number of designated Notified Bodies and their slow designation have caused significant delays in conformity assessments, impacting market access for both new and existing devices.
- **Inflexible Regulatory Framework:** The current one-size-fits-all regulatory approach doesn't account for the specific needs of SMEs, breakthrough technologies, niche diagnostics, orphans IVDs, AI-driven innovations…
- **Barriers to Innovation and Market Access:** The lengthy certification process, high costs, and complex administrative requirements have discouraged investment in innovative technologies, prompting many manufacturers to prioritise non-EU markets over the EU.
- **Ineffective Derogation Mechanisms:** The EU-wide derogation mechanism (Article 54 IVDR) has never been used, leading companies to rely on national exemptions instead. This has resulted in fragmented regulatory responses during public health emergencies, such as COVID-19.
- Important **elements of the regulatory infrastructure were set late** (Common Specifications, EURLs, Expert Panels… *please bring your own example of how this has influenced your business*)

**Question 6.17** MedTech Europe plans to strongly disagree that the extended transition periods of the Regulation have addressed the concerns.

**Sub-Question 6.18**: Considerations for the Free Text Box (please address these or any other points you feel particularly strongly about):

- The extended transitional periods have provided the immediate relief to the system and helped maintain the devices available to patients. Considerable work has already gone into addressing short-term implementation challenges by the European Commission and other stakeholders. Legislators have given a total of two extensions to the transition timelines, to ensure IVDs remain available to laboratories and patients, as the common belief was that system readiness including for example, sufficient Notified Body capacity, was lagging.

[5] See online dictionary, https://dictionary.cambridge.org/dictionary/english/duly

- Unfortunately, it has become clear that without addressing the core deficiencies, such extensions only postpone the impact. 'More implementation' alone will not be enough.

### B. Transparency and traceability

**Question 6.45** MedTech Europe plans to strongly disagree with:

- Transparency of information on devices in the EU
- Traceability of devices in the EU
- Trust in the regulatory system of medical devices

**Sub-Question 6.47** Transparency - Considerations for the Free Text Box (please address these or any other points you feel particularly strongly about):

- **Barrier to Transparency**: EUDAMED is not fully functional, meaning it's not legally applicable or fully populated, and public access to information via the database is incomplete.
- **Interpretation and Application Issues**: Confusion exists regarding who should upload the Summary of Safety and Performance to EUDAMED (Notified Body vs. manufacturer) and what it should contain (e.g., whether a patient section is required).
- **Impact of EUDAMED Timeline Delays**: Consider how changes and delays in the EUDAMED development timelines have affected your implementation project, including planning, budgeting, and IT resource allocation.
- **Feedback on EUDAMED Testing**: If you participated in EUDAMED testing, reflect on how your feedback was incorporated by the EUDAMED Support and Development team. Assess whether the database meets your needs and is efficient and user-friendly.
- **UDI/Device Submission Planning**: Ensure your company has the necessary technical and regulatory information for smooth execution and transition. Challenges may include for example, the inability to correct data before linking to a certificate or vigilance case, burdensome manual processes, excessive data requirements, misaligned technical documents, and specifications that hinder high-quality data entry into EUDAMED. EUDAMED requests more information than legally required, such as for non-registered devices, legacy devices, CIPS application details, and Manufacturer Incident Reporting forms.

**Sub-Question 6.49** Traceability - Considerations for the Free Text Box (please address these or any other points you feel particularly strongly about):

- **Traceability vs. Tracking:** Traceability identifies a device within the supply chain, a practice that has been in place for decades by economic operators (batch/lot). It's not a new concept. However, due to technological limitations, users often rely on alternative means (e.g., shipping papers, emails) to request UDI-DI/PI information, while manufacturers comply by labeling products with the required UDI-DI/PI. Additionally, mass data downloads of up-to-date medical device information from EUDAMED are currently unavailable for users/hospitals.
- **EUDAMED Constraints and Traceability Barriers:** EUDAMED has built-in limitations that hinder traceability. For example, mergers and acquisitions cannot be efficiently managed (e.g., devices can't be transferred to a new legal entity). Many device registration elements are not updatable, requiring a new UDI-DI and "new" device registration for data errors or business events like Notified Body changes. This leads to unnecessary tasks for manufacturers and Notified Bodies, creates multiple records in EUDAMED, and poses risks to traceability during vigilance events.

**Sub-Question 6.51** Trust - Considerations for the Free Text Box (please address these or any other points you feel particularly strongly about) *Note: The question on trust is aiming to assess the effect of the Regulation, and it is not about trust in devices.*

- Non-EU countries that once relied on the European CE marking are moving away from this system, leading to uncertainty about whether devices are lawfully placed on the market. For example, Brazil no longer uses CE marking as a basis for reliance.

- The transition periods outlined in the Regulations may not have been realistic given the scale of required changes, leading to multiple amendments. Additionally, frequent updates to MDCG guidance documents have not contributed to a stable or trustworthy regulatory environment.

- If the question is about the trust of healthcare professionals and patients in the regulatory system, MedTech Europe plans to "strongly disagree." The IVDR's impact on device availability and innovation moving away from Europe has weakened trust in the European regulatory framework. Similarly, the transition from the IVD Directive to IVDR has further diminished confidence in the regulatory system.

## C. Functioning of the internal market

**Question 6.68**

Members who plan to (strongly) disagree with the below questions should provide their own rationale and examples they have experienced, for the following Free Text Boxes:

MedTech Europe *might* disagree with:
The rules being applied fairly and impartially to all stakeholders before a device is CE-marked.
**Sub-Question 6.73** Considerations for Free Text Box (please speak to these or other points you feel particularly strongly about): for example, some but not all Notified Bodies may provide structured dialogues, conduct of multi-country performance studies
The rules being applied fairly and impartially to all stakeholders after a device is CE-marked,
**Sub-Question 6.73** Considerations for Free Text Box (please speak to these or other points you feel particularly strongly about): (for example, Notified Bodies may treat change notification process, PSUR or vigilance reviews differently…)

MedTech Europe plans to strongly disagree with:
The IVD Regulation has contributed with the creation of an **equal playing field for all economic operators**, regardless of company size or market position.

**Sub-Question 6.73** Considerations for Free Text Box (please speak to these or other points you feel particularly strongly about):

- The feasibility of conducting performance studies varies by country, as authorisation and notification requirements differ significantly across the EU.
- An SME company may have a more difficult time finding a Notified Body.
- Some Member States have national distributor databases

**Sub-Question 6.81** MedTech Europe plans to take a neutral stance on the extent to which guidance documents produced by the Medical Device Coordination Group enhance legal clarity on the provisions of the Regulation.
*Important!* Note: disagreeing or strongly disagreeing does not open up sub questions and there is no Text Box to elaborate on these aspects here.

## D. Competitiveness and Innovation

**Question 6.82** MedTech Europe plans to strongly disagree with the contribution that the Regulation has made to the **competitiveness** of the medical device sector in the EU and **innovation** in the medical device sector taking place in the EU.

**Sub-Questions 6.82 and 6.83** Considerations for the Free Text Box (please address these or any other points you feel particularly strongly about):

- The unpredictability, complexity, and burden of the regulations means that many devices on the market today as well as new, innovative medical technologies are not reaching patients in Europe as they should[6]. Add your own experience of how this is impacting your company.
- You may wish to comment on how you are experiencing the perspective of non-EU regulators (e.g. Brazil, UK and Australia) when they look at the value of CE-marking.
- The competitiveness of the wider industry and even the viability of many small businesses (SMEs) are at risk[7].
- Lack of clarity on the new requirements and timelines by non-EU/non-EEA authorities which may lead to less trust and ultimately cause a barrier to competitiveness

## E. EU added value

**Question 6.91** MedTech Europe plans to agree that it is preferable to have one EU Regulation in this field instead of individual national regulations covering the same aspects.

## F. Relevance and coherence of the EU rules on medical devices

**Question 6.92** MedTech Europe plans to strongly disagree that the IVD Regulation addresses:

*Important!* Note: disagreeing or strongly disagreeing does not open up sub questions and there is no Text Box to elaborate on these aspects here.

**Emerging health challenges and evolving patient needs** – considerations for members:

- IVDR Article 54 (EU-Level Derogations) has proven impractical. During the pandemic, manufacturers had to rely on burdensome national derogations, as the EU-wide mechanism was not activated.
- The mechanism is not designed for rapid decision-making.
- There is no way to group devices under a derogation request.
- The lack of an effective EU-wide emergency approval pathway means that in future health crises, manufacturers cannot rely on a single, streamlined process to bring critical diagnostics to market.

Provide your own examples of emerging health challenges which are unaddressed because of IVDR. You may wish to suggest solutions.

**Emerging technological (including digital) or scientific progress in the sector** – considerations for members:

- The IVDR's complex and costly pre-market regulatory requirements, combined with long certification timelines, delay the access of new technologies, including digital health solutions, AI-driven devices, and next-generation implants. Many innovative products face longer time-to-market in the EU compared to other regions, putting Europe at a disadvantage in global medical technology innovation (please provide examples)

[6] The IVDR has dramatically affected the choice of the EU as the main option for a first regulatory approval by large manufacturers and SMEs, with a reduction of 40% and 12% respectively. By contrast, the choice of other geographies increased significantly. Source: MedTech Europe 2024 IVDR & MDR Survey Report [link]

[7] For example, signs that start-ups smaller & medium-sized business are closing can be found under these surveys: Key takeaways under Dutch IGJ 2023 survey report, Manufacturers, please take timely action to meet IVDR requirements; Also see survey report by the German Chamber of Commerce and Industry (DIHK), the MedicalMountains cluster initiative, and the German industry association SPECTARIS '*Current assessment of the German medical device manufacturers on the effects of the EU MDR*', December 2023: while the report did not address business closure specifically, the percentages of planned and reported discontinuations of devices are severe enough especially for smaller companies, to indicate that their business viability is at risk.

- The current framework does not accommodate the iterative nature of AI, where algorithms improve over time, leading to regulatory uncertainty and hindering investment in digital health. The IVDR does not include a streamlined approval pathway for niche, orphan, breakthrough or high-impact medical technologies. Other regions, such as the US (FDA's Breakthrough Devices Program), provide faster regulatory routes for innovative devices, making them more attractive markets for first launches.

**Potential future technological and scientific innovation in the sector (e.g., research and development)** – considerations for members:

- The answer to this question might be very similar to the one above. IVDR, in its current form, does not foster current and future technological and scientific innovation. Instead, its framework can discourage investment in breakthrough, niche and orphan (or diagnostics for rare diseases) technologies.

**Question 6.97** MedTech Europe plans to strongly disagree that provisions in the IVD Regulation are coherent with one another and that the IVDR is coherent with MDR.

Considerations for the Free Text Box (please address these or any other points you feel particularly strongly about):

**Sub-Question 6.98 and 6.99**

- Consider where elements within the Regulation are confusing for you or seem to contradict basic principles.
- Illustrative examples only (please provide examples which you find important):
    - IVDR art 48 is not coherent with the IVDR Annex IX
- Consider where elements within the IVD Regulation is not coherent with MD Regulation
    - It is interpreted that routine blood draws taken for the purpose of a performance study means that the performance study must be applied for. This interpretation depends on a definition of 'surgically invasive' which appears only under the MD Regulation and which should not apply for the IVD Regulation.

## G. Efficiency of the EU rules on medical devices

MedTech Europe plans to strongly disagree with the following statements across all four phases, based on its experience over the past three years:

*Important!* Note: disagreeing or strongly disagreeing does not open up sub questions and there is no Text Box to elaborate on these aspects here.

- The costs of complying with IVDR for the listed activities are reasonable.
- The administrative costs for the listed activities are acceptable.
- The costs of IVDR compliance for the listed activities will decrease once the regulation is fully implemented.
- The administrative costs for the listed activities will decline once the regulation is fully in effect.

**Phase 1 (Question 6.100):** activities related to generating evidence on the safety and performance of devices; activities related to clinical investigations; activities related to setting up quality management systems; activities for the designation of notified bodies under the Regulation

**Phase 2 (Question 6.101):** activities concerning the initial certification of devices and the maintenance of certificates; activities concerning the first placing on the market or putting into service devices for which the conformity assessment does not involve a notified body; activities related to derogations to the conformity assessment

**Phase 3 (Question 6.102):** activities for the compliance with post market obligations; activities related to vigilance; activities related to market surveillance

**Phase 4 (Question 6.103):** activities for providing information on devices or certificates; activities providing guidance to the sector

## H. Additional information

**Question 8.1** Please feel free to include any additional relevant points that you feel important and that are NOT covered by the questionnaire itself. The free text field allows for 5000 characters including spaces.

MedTech Europe, as of this moment, plans to include points on recertification, governance and any explanations/clarifications of our answers to the particular parts of the questionnaire.

## 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.