Contribution ID: 0927005d-9899-4ae0-a7c6-583e50eb942c
Date: 20/03/2025 17:00:48

# Public consultation: targeted evaluation of the EU rules on medical devices and in vitro diagnostics

Fields marked with * are mandatory.

## 1 Introduction

This is the first evaluation carried out by the Commission to assess the current EU rules on medical devices and in vitro diagnostic medical devices.
The Regulations that are being evaluated are the Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) which were adopted in 2017 and aim to ensure that only safe and effective devices are on the EU market, to protect patient safety and public health whilst supporting innovation .
Considering the extent of the changes introduced by the Regulations, transition periods were foreseen to ensure a smooth transition to the new rules. These transition periods are still currently ongoing and, due to a number of challenges, have been extended multiple times compared to the ones initially foreseen.
In view of the significant challenges encountered with transitioning to the new rules, while article 121 MDR and 111 IVDR require the Commission to conduct an evaluation by May 2027, the Commission has decided to launch already in 2024 a targeted evaluation of the Regulations. As the Regulations are not yet fully implemented, it is acknowledged that only the parts of the Regulations that are implemented can be assessed in the evaluation.
The evaluation aims to assess the performance of the legislation. Particular attention will be placed on the impact of the legislation on the availability of devices, including ‘orphan devices’ and devices for small populations, as well as the development of innovative devices in the EU. Special attention in the assessment will be given to costs and administrative burdens, especially for SMEs, as well as the benefits stemming from the implementation of legislation.
Further information on the Regulations can be found on the Commission website.

## 2 About you

### * 2.1 Language of my contribution

- Bulgarian
- Croatian
- Czech
- Danish

- Dutch
- English
- Estonian
- Finnish
- French
- German
- Greek
- Hungarian
- Irish
- Italian
- Latvian
- Lithuanian
- Maltese
- Polish
- Portuguese
- Romanian
- Slovak
- Slovenian
- Spanish
- Swedish

*2.2 I am giving my contribution as

- Academic/research institution
- Business association
- Company/business
- Consumer organisation
- EU citizen
- Environmental organisation
- Non-EU citizen
- Non-governmental organisation (NGO)
- Public authority
- Trade union
- Other

* 2.3 You are giving your contribution as a company/business or as a business organisation.
Please specify whether you are giving your contribution as one of the following categories

*Maximum 1 selection(s)*

- [ ] Economic operator (Art 2(35) MDR / Art 2(28) IVDR)
- [ ] Notified body designated under MDR/IVDR (Art 2(42) MDR / Art 2(34) IVDR)
- [x] Other company / business

* 2.8 First name

Katalin

* 2.9 Surname

MÁTÉ

* 2.10 Email (this won't be published)

regulatory@medtecheurope.org

* 2.14 Organisation name

*255 character(s) maximum*

MedTech Europe

* 2.15 Organisation size

- ( ) Micro (1 to 9 employees)
- (•) Small (10 to 49 employees)
- ( ) Medium (50 to 249 employees)
- ( ) Large (250 or more)

2.16 Transparency register number

Check if your organisation is on the transparency register. It's a voluntary database for organisations seeking to influence EU decision-making.

433743725252-26

* 2.17 Country of origin

Please add your country of origin, or that of your organisation.

*This list does not represent the official position of the European institutions with regard to the legal status or policy of the entities mentioned. It is a harmonisation of often divergent lists and practices.*

- Afghanistan
- Åland Islands
- Albania
- Algeria
- American Samoa
- Andorra
- Angola
- Anguilla
- Antarctica
- Antigua and Barbuda
- Argentina
- Armenia
- Aruba
- Australia
- Austria
- Azerbaijan
- Bahamas
- Bahrain
- Bangladesh
- Barbados
- Belarus
- Belgium
- Belize
- Benin
- Bermuda
- Bhutan
- Djibouti
- Dominica
- Dominican Republic
- Ecuador
- Egypt
- El Salvador
- Equatorial Guinea
- Eritrea
- Estonia
- Eswatini
- Ethiopia
- Falkland Islands
- Faroe Islands
- Fiji
- Finland
- France
- French Guiana
- French Polynesia
- French Southern and Antarctic Lands
- Gabon
- Georgia
- Germany
- Ghana
- Gibraltar
- Greece
- Greenland
- Libya
- Liechtenstein
- Lithuania
- Luxembourg
- Macau
- Madagascar
- Malawi
- Malaysia
- Maldives
- Mali
- Malta
- Marshall Islands
- Martinique
- Mauritania
- Mauritius
- Mayotte
- Mexico
- Micronesia
- Moldova
- Monaco
- Mongolia
- Montenegro
- Montserrat
- Morocco
- Mozambique
- Myanmar/Burma
- Saint Martin
- Saint Pierre and Miquelon
- Saint Vincent and the Grenadines
- Samoa
- San Marino
- São Tomé and Príncipe
- Saudi Arabia
- Senegal
- Serbia
- Seychelles
- Sierra Leone
- Singapore
- Sint Maarten
- Slovakia
- Slovenia
- Solomon Islands
- Somalia
- South Africa
- South Georgia and the South Sandwich Islands
- South Korea
- South Sudan
- Spain
- Sri Lanka
- Sudan
- Suriname

- Svalbard and Jan Mayen
- Bolivia
- Grenada
- Namibia
- Sweden
- Bonaire Saint Eustatius and Saba
- Guadeloupe
- Nauru
- Switzerland
- Bosnia and Herzegovina
- Guam
- Nepal
- Syria
- Botswana
- Guatemala
- Netherlands
- Taiwan
- Bouvet Island
- Guernsey
- New Caledonia
- Tajikistan
- Brazil
- Guinea
- New Zealand
- Tanzania
- British Indian Ocean Territory
- Guinea-Bissau
- Nicaragua
- Thailand
- British Virgin Islands
- Guyana
- Niger
- The Gambia
- Brunei
- Haiti
- Nigeria
- Timor-Leste
- Bulgaria
- Heard Island and McDonald Islands
- Niue
- Togo
- Burkina Faso
- Honduras
- Norfolk Island
- Tokelau
- Burundi
- Hong Kong
- Northern Mariana Islands
- Tonga
- Cambodia
- Hungary
- North Korea
- Trinidad and Tobago
- Cameroon
- Iceland
- North Macedonia
- Tunisia
- Canada
- India
- Norway
- Türkiye
- Cape Verde
- Indonesia
- Oman
- Turkmenistan
- Cayman Islands
- Iran
- Pakistan
- Turks and Caicos Islands
- Central African Republic
- Iraq
- Palau
- Tuvalu
- Chad
- Ireland
- Palestine
- Uganda
- Chile
- Isle of Man
- Panama
- Ukraine
- China
- Israel
- Papua New Guinea
- United Arab Emirates
- Christmas Island
- Italy
- Paraguay
- United Kingdom
-
-
-
-

| | | | |
|---|---|---|---|
| Clipperton | Jamaica | Peru | United States |
| Cocos (Keeling) Islands | Japan | Philippines | United States Minor Outlying Islands |
| Colombia | Jersey | Pitcairn Islands | Uruguay |
| Comoros | Jordan | Poland | US Virgin Islands |
| Congo | Kazakhstan | Portugal | Uzbekistan |
| Cook Islands | Kenya | Puerto Rico | Vanuatu |
| Costa Rica | Kiribati | Qatar | Vatican City |
| Côte d'Ivoire | Kosovo | Réunion | Venezuela |
| Croatia | Kuwait | Romania | Vietnam |
| Cuba | Kyrgyzstan | Russia | Wallis and Futuna |
| Curaçao | Laos | Rwanda | Western Sahara |
| Cyprus | Latvia | Saint Barthélemy | Yemen |
| Czechia | Lebanon | Saint Helena Ascension and Tristan da Cunha | Zambia |
| Democratic Republic of the Congo | Lesotho | Saint Kitts and Nevis | Zimbabwe |
| Denmark | Liberia | Saint Lucia | |

The Commission will publish all contributions to this public consultation. You can choose whether you would prefer to have your details published or to remain anonymous when your contribution is published. **Fo r the purpose of transparency, the type of respondent (for example, 'business association, 'consumer association', 'EU citizen') country of origin, organisation name and size, and its transparency register number, are always published. Your e-mail address will never be published.** Opt in to select the privacy option that best suits you. Privacy options default based on the type of respondent selected

* 2.19 **Contribution publication privacy settings**

The Commission will publish the responses to this public consultation. You can choose whether you would like your details to be made public or to remain anonymous.

- **Anonymous**

  Only organisation details are published: The type of respondent that you responded to this consultation as, the name of the organisation on whose behalf you reply as well as its transparency number, its size, its country of

origin and your contribution will be published as received. Your name will not be published. Please do not include any personal data in the contribution itself if you want to remain anonymous.

- **Public**
  Organisation details and respondent details are published: The type of respondent that you responded to this consultation as, the name of the organisation on whose behalf you reply as well as its transparency number, its size, its country of origin and your contribution will be published. Your name will also be published.

☑ I agree with the personal data protection provisions

## 4 Scope of the questionnaire for stakeholders

The questionnaire is divided into two parts. The first part will cover medical devices (part A) and the second part will cover in vitro diagnostic medical devices (part B).
**Medical devices**, hereinafter referred to as 'device', are defined as: Any instrument, apparatus, appliance, software, implant, reagent, material, or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: (-) diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease, (-) diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability, (-) investigation, replacement, or modification of the anatomy or of a physiological or pathological process or state, (-) providing information by means of in vitro examination of specimens derived from the human body, including organ, blood, and tissue donations; and which does not achieve its principal intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its function by such means. The following products shall also be deemed to be medical devices: (-) devices for the control or support of conception (-) products specifically intended for the cleaning, disinfection or sterilization of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point. [Source: MDR Regulation (EU) 2017/745]

***In vitro* diagnostic medical devices (IVDR)** are defined as : Any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on one or more of the following: a) concerning a physiological or pathological process or state; b) concerning congenital physical or mental impairments; c) concerning the predisposition to a medical condition or a disease; d) to determine the safety and compatibility with potential recipients; e) to predict treatment response or reactions; f) to define or monitoring therapeutic measures. Specimen receptacles shall also be deemed to be in vitro diagnostic medical devices [Source: IVDR Regulation (EU) 2017/746]

### 4.1 Please indicate to which questionnaire(s) you would like to reply:

☑

Medical devices (MDR)

☑ *In vitro* diagnostic medical devices (IVDR)

## 5 Questions on medical devices (MDR)

### MD - Protection of health for patients and users

*5.1 To what extend do you agree that the Regulation has contributed to protecting the health of **patients** in relation to medical devices?

- ○ Strongly disagree
- ○ Disagree
- ○ Neutral
- ◉ Agree
- ○ Strongly agree
- ○ Not applicable/ I don't know

*5.2 To what extend do you agree that the Regulation has contributed to protecting the health of **users** in relation to medical devices?

*For the purpose of this question, 'users' are understood as any healthcare professional or lay person who uses a device.*

- ○ Strongly disagree
- ○ Disagree
- ◉ Neutral
- ○ Agree
- ○ Strongly agree
- ○ Not applicable/ I don't know

5.3 Based on the experience of the last 3 years, to what extent do you agree with the following:

| | Strongly disagree | Disagree | Neutral | Agree | Strongly agree |
|---|---|---|---|---|---|
| * The **performance** of CE-marked devices is good | ○ | ○ | ○ | ○ | ◉ |
| * The CE-marked devices are **safe** | ○ | ○ | ○ | ○ | ◉ |
| * There are robust **quality checks** before a device is placed on the market | ○ | ○ | ○ | ○ | ◉ |
| * Specific **patient needs are met** through the use of in-house and custom-made devices | ○ | ○ | ◉ | ○ | ○ |

| | | | | | |
|---|---|---|---|---|---|
| * **Safety issues** are adequately identified and addressed when detected | ○ | ○ | ○ | ○ | ◉ |
| * The sector and its industry is **duly regulated** | ◉ | ○ | ○ | ○ | ○ |

* 5.14 What do you think contributed to the sector not being duly regulated? Please select all that apply.

- [x] The ways of working between notified bodies, economic operators, competent authorities and the European Commission is inefficient
- [x] The tools and processes in the Regulations are not in place (e.g. EUDAMED, EU reference laboratories, coordinated assessment of clinical investigations and performance studies etc.)
- [x] Divergences in interpretation and application of the Regulation by competent authorities, European Commission and notified bodies
- [x] Lack of clarity on the legal requirements for stakeholders
- [x] The requirements in the Regulation are too burdensome
- [ ] Lack of resources (financial/human/technical)
- [ ] Lack of clinical and scientific expertise by economic operators
- [ ] Lack of clinical and scientific expertise by notified bodies
- [x] Lack of clinical and scientific expertise by competent authorities
- [ ] Lack of clinical and scientific expertise by the European Commission
- [ ] Divergent/conflicting economic interests between public and private parties
- [x] Other

* 5.15 Please specify

The structure and many elements of the MDR in theory are fit for purpose for supporting it to achieve its objectives as set out in preambles 1 and 2. However, both present and absent elements of the legal text, the way in which the regulatory system has been implemented and ongoing infrastructure challenges are resulting in significant systemic deficiencies. While MDR provides a good basis for device safety and performance, it falls short in fulfilling other objectives such as providing a robust and sustainable regulatory system which supports innovation and the great many SMEs active in the sector. For these reasons, MedTech Europe strongly disagrees that the regulatory system is duly regulated.

The governance of the system is in need of an overhaul to put in place a single, accountable governance structure. Today's regulatory framework has poor mechanisms in place for allocating Notified Body resources and using them in an optimal way in the system to ensure device safety and performance: instead MDR tends to take uniform approaches (with certain considerations by risk class and certain device types) without consideration of manufacturer and device history. This can stifle innovation and negatively impact the availability of current and future medical devices. The multitude of stakeholders involved, without a clear responsible entity overseeing the system, prevents effective support for competitiveness and hampers necessary course correction actions.

Some additional examples (list not exhaustive):

- Lack of regulatory predictability and clarity: Manufacturers require a stable and predictable regulatory environment to operate effectively and make devices available for health systems and patients. The lengthy certification process, high costs, and complex administrative requirements—some of which are frequently reviewed or altered in response to MDCG guidance—divert resources away from innovation and toward regulatory compliance activities. This complexity discourages investment, prompting many manufacturers to seek markets outside the EU for their first regulatory approval.

- Differing interpretations between and within Notified Bodies can arise: Inconsistent interpretations by reviewers within the same Notified Body or between different Notified Bodies held by the same manufacturer, can create challenges with heavy resource and even ability-to-market implications. They also create an uneven playing field, as different Notified Bodies treat manufacturers of the same type of device differently.

- Limited capacity and availability of Notified Bodies: low numbers of designated Notified Bodies during the initial stages of MDR implementation led to significant delays in conformity assessments, severely affecting availability of both existing and new devices. To an extent the lack in Notified Bodies' capacity was mitigated by provision of extended transitional periods.

- Innovation and the regulatory framework: Obstacles exist to device optimization (improvement) activities. The current approach fails to account for the specific needs of Small-Medium Enterprises (SMEs), breakthrough technologies, orphan devices, and AI-driven innovations. Devices developed under previous regulatory environments that have demonstrated safety and are considered well-established by experts (but may not be listed in the current well established technologies list per MDR) may face the need for new evidence generation. This exercise does not add value for patients, and its cost outweighs the benefits. Furthermore, healthcare professionals (HCPs) are often unwilling to participate in such studies, potentially leading to the removal of frequently used devices from the market.

- Lack of effective derogation mechanisms for public health emergencies: The derogation mechanism mandated by Article 59 MDR has proven ineffective in addressing public health emergencies at an EU level. Companies have been forced to rely on national-level exemptions, leading to fragmented regulatory responses for example during the COVID-19 pandemic. Manufacturers applying for derogations in each state received different responses for the same application resulting in products being available sporadically across Europe.

* 5.17 To what extent do you agree that the extended transition periods of the Regulation have addressed concerns you/the members you represent had?

- ○ Strongly disagree
- ◉ Disagree
- ○ Neutral
- ○ Agree
- ○ Strongly agree
- ○ Not applicable/ I don't know

## * 5.18 Please explain which concerns the extension of the transition periods did not address

The two extensions ensured a somewhat greater availability of designated Notified Bodies before the deadlines of May 2024, but did not fully address capacity nor especially efficiency issues which persist in the Notified Bodies' system. However, they largely postponed the underlying systemic deficiencies which contributed to the need for extended transition time, including lack of system predictability, long conformity assessment timelines, high complexity and costs for gaining and maintaining CE-marking.

In 2018, MedTech Europe published 3 papers with recommendations for successful MDR implementation: 1) Early availability and capacity of Notified Bodies; 2) Investment in resources and clarification of the governance system; and 3) Clarity and consistent application of transitional arrangements.

MedTech Europe considers that insufficient resources and medtech-specific expertise have been allocated by the European Commission and Member States towards the implementation of the system. The extended time did allow for a governance system with the MDCG to be set up and clarity around transitional arrangements to be provided.

Today's regulatory system is burdened by complexity, inefficiency, inconsistent interpretation among Competent Authorities and Notified Bodies, redundant requirements, and a lack of predictability regarding fees, timelines, and processes. Without addressing these fundamental issues, extensions merely delay the negative consequences rather than resolving them.

Another bottleneck in Notified Bodies' capacity is anticipated with the renewal of existing MDR certificates, valid for five years. The re-certification will coincide with the end of the extended transition timelines and other Notified Bodies' work, including change notification and post-market surveillance. Increasing implementation efforts will not suffice. Systemic improvements to address MDR deficiencies are essential.

While the extensions were needed for many manufacturers and their devices, they have had unintended consequences, including a weakening of trust in the CE mark in several jurisdictions outside the EU, uncertainty regarding the regulatory status of devices within the EU, and an increased burden on Notified Bodies and manufacturers. This was in part due to additional requests and misunderstandings from non-EU authorities, particularly in regions that previously relied heavily on CE marking.

Outside the EU, reliance on CE marking varies by country. It was once essential for market access in countries without dedicated regulations, benefiting EU exporters. However, this reliance has weakened over time, with several countries now showing less or no dependence on CE marking. This trend is partially attributed to the reform of the EU legislation brought by the MDR. The complexity of changes, the transition which is still underway and not tracking the original anticipated timeline, have resulted in confusion and even a degree of distrust among non-EU regulators. A series of questions and issues impacting product registrations in third countries while leveraging CE certificates has arisen. As a result, industry is concerned that the CE marking used as evidence of regulatory compliance under MDR has lost much of its international credibility. E.g. Brazil introduced last year (IN 290/2024) a reliance pathway where market authorisation certificates from the "Equivalent Foreign Regulatory Authorities" (US, Canada, Japan, and Australia – all of which are full members of the Medical Device Single Audit Program, MDSAP) are accepted for expedited review for market authorisation (registration) in Brazil for certain medical devices. Currently, this process does not include CE marking, even though, according to April 2024 data from ANVISA (Brazilian Health Authority), EU products represent the largest percentage of devices of foreign origin in Brazil.

Other countries such as Switzerland, UK and Australia, which solely relied on CE marking, are considering additional forms of reliance to ensure devices' availability.

To restore trust in CE marking, an active, frequent presence of the European Commission in international fora and engagement in bilateral exchanges with other regulatory authorities would critically contribute to raise awareness about the latest developments in the European regulatory framework for technologies. The large number of attendees to the info session for non-EU/non-EEA stakeholders on 04 July 2024 (800+) is a clear indicator of the high degree of interest of international stakeholders in the evolving EU regulatory framework. Communication should be more timely: for example, the 2024 factsheet for non-EU/non-EEA authorities was released two years after the publication of Amendment 2023/607, with this delay contributing to the level of uncertainty outside of the EU.

## MD - Transparency and traceability

For the purpose of answering questions in this survey, please note that the terminology used in this section should be understood as follows:

**Transparency:** information about devices that are on the EU market (includes data regarding characteristics, the clinical data and the conformity assessment path of certain devices),

**Traceability:** the ability to precisely identify and track a specific medical device on the EU market.

5.45 Based on the experience of the last 3 years, to what extent do you agree that the regulation has contributed to achieving:

| | Strongly disagree | Disagree | Neutral | Agree | Strongly agree | Not applicable/ I don't know |
|---|---|---|---|---|---|---|
| * **transparency** of information on devices in the EU | ◉ | ○ | ○ | ○ | ○ | ○ |
| * **traceability** of devices in the EU | ◉ | ○ | ○ | ○ | ○ | ○ |
| * **trust** in the regulatory system of medical devices | ◉ | ○ | ○ | ○ | ○ | ○ |

* 5.46 What do you see as the most important barrier to the transparency of information on devices in the EU? Please select all that apply.

- ☑ The ways of working between notified bodies, economic operators, competent authorities and the European Commission is inefficient
- ☑ The tools and processes in the Regulations are not in place (e.g. EUDAMED, EU reference laboratories, coordinated assessment of clinical investigations and performance studies etc.)
- ☑ Divergences in interpretation and application of the Regulation by competent authorities, European Commission and notified bodies
- ☑

Lack of clarity on the legal requirements for stakeholders

- [ ] The requirements in the Regulation are too burdensome
- [ ] Lack of resources (financial/human/technical)
- [ ] Lack of clinical and scientific expertise by economic operators
- [ ] Lack of clinical and scientific expertise by notified bodies
- [ ] Lack of clinical and scientific expertise by competent authorities
- [ ] Lack of clinical and scientific expertise by the European Commission
- [ ] Divergent/conflicting economic interests between public and private parties
- [x] Other

*5.47 Please specify

The biggest barrier to transparency is the absence of a fully operational EUDAMED database: it is neither legally applicable nor fully populated. Beyond the availability of a mandatory database, there are issues with the development and efficiency of EUDAMED which will hamper transparency of information for all actors and stakeholders.

Inefficiency in collaboration and communication with stakeholders:
o EUDAMED is being developed without closely monitoring the needs of economic operators and Notified Bodies, despite them being responsible for submitting and maintaining the vast majority of the required data. Additionally, insufficient investment has gone into considering user needs—such as those of hospitals, healthcare professionals and patients.
o Economic operators hesitate to submit device information before the legal deadlines due to uncertainty about data update rules and mechanisms – and the possibility that incorrect submissions could trigger need for new UDID. The lack of a correction function and limited discard option (only available before a certificate or vigilance case is linked) further complicates compliance. Moreover, the technical documentation and specifications provided are not yet qualified as sufficient for EUDAMED implementation, raising concerns about data quality.

Divergences in regulatory interpretation and application:
o There are inconsistencies in how the Summary of Safety and Clinical Performance (SSCP) is handled, particularly regarding who is responsible for uploading it to EUDAMED (Notified Body or manufacturer?) and whether a patient section is required.
o EUDAMED demands information beyond legal requirements, including the registration of non-reportable devices, legacy devices, extensive data for Clinical Investigation applications, and excessive details in the Manufacturer Incident Reporting form.

Future considerations:
o Shifting EUDAMED timelines have led to resource shortages within the industry, particularly affecting smaller companies by creating uncertainty about when major IT projects should be scheduled.
o EUDAMED requirements are anticipated to be burdensome (manual processes, increased number of data elements, minimal viable product approach)

*5.48 What do you see as the most important barrier affecting the traceability of devices in the EU? Please select all that apply.

- [x]

- [ ] The ways of working between notified bodies, economic operators, competent authorities and the European Commission is inefficient
- [x] The tools and processes in the Regulations are not in place (e.g. EUDAMED, EU reference laboratories, coordinated assessment of clinical investigations and performance studies etc.)
- [x] Divergences in interpretation and application of the Regulation by competent authorities, European Commission and notified bodies
- [x] Lack of clarity on the legal requirements for stakeholders
- [ ] The requirements in the Regulation are too burdensome
- [ ] Lack of resources (financial/human/technical)
- [ ] Lack of clinical and scientific expertise by economic operators
- [ ] Lack of clinical and scientific expertise by notified bodies
- [ ] Lack of clinical and scientific expertise by competent authorities
- [ ] Lack of clinical and scientific expertise by the European Commission
- [ ] Divergent/conflicting economic interests between public and private parties
- [x] Other

*5.49 Please specify

The identification of the device in the supply chain (traceability) is ensured through the storage of the UDI by economic operators (and by health institutions and health professionals for at least Class III implants). Traceability is not a new concept, it is applied by manufacturers for decades. This area is new for hospitals, as they must now retain and store UDI information (UDI-DI and UDI-PI of Class III implantable medical devices) and include UDI-DI on implant cards and in patient records. Under national laws the traceability requirement is expanded to other types/classes of devices e.g. in Belgium and in Italy.
Note: tracking which is included in the explanation of traceability for this question is different.

Inefficiency in collaboration and communication / missing tools:
• There is no functionality yet implemented for mass data downloads of up-to-date medical device information from EUDAMED, limiting access for users, including hospitals and healthcare professionals to UDI and device data.
• EUDAMED has built-in constraints that hinder the efficient management of mergers and acquisitions: the system does not allow for the transfer of devices to a new legal entity, preventing the proper maintenance of traceability and vigilance history of the same device.

Divergences in regulatory interpretation and application:
• A significant number of device registration elements in EUDAMED are non-updatable: they cannot be changed without assigning a new device identifier (UDI-DI). This forces manufacturers to create a new UDI-DI and register a "new" device in EUDAMED when errors of the submitted device information are identified or when valid business events occur, such as change of Notified Body. This leads to multiple records for the same device in the database, undermining vigilance history.

Lack of clarity on legal requirements:
• Non-sterile implants' traceability: UDI not on the label but to be supplied by other means (non-sterile

multi-device surgical sets are delivered without packaging/without label ready for sterilization in the hospital before surgery).

Requirements too burdensome:

- Unlike the FDA, there is no legal mechanism within the EU framework for granting exemptions or proposing alternatives for specific device groups.
- The introduction of Master UDI-DI presents a disproportionate barrier to traceability.
- Due to the lack of technological solutions such as “scanned as delivered” at hospitals and healthcare professionals, users request UDI-DI/PI information via alternative means (e.g., shipping papers, emails). At the same time, manufacturers remain compliant with regulatory requirements by labelling their products with UDI-DI and UDI-PI accordingly.
- Regulatory enforcement discretion needed for contact lenses (comes to an end in the US, register flat at DI level with changes to GUDID to better capture the parameters)

* 5.50 What do you see as the most important barrier to building trust in the regulatory system of medical devices in the EU? Please select all that apply.

- [x] The ways of working between notified bodies, economic operators, competent authorities and the European Commission is inefficient
- [x] The tools and processes in the Regulations are not in place (e.g. EUDAMED, EU reference laboratories, coordinated assessment of clinical investigations and performance studies etc.)
- [x] Divergences in interpretation and application of the Regulation by competent authorities, European Commission and notified bodies
- [x] Lack of clarity on the legal requirements for stakeholders
- [x] The requirements in the Regulation are too burdensome
- [x] Lack of resources (financial/human/technical)
- [ ] Lack of clinical and scientific expertise by economic operators
- [ ] Lack of clinical and scientific expertise by notified bodies
- [x] Lack of clinical and scientific expertise by competent authorities
- [ ] Lack of clinical and scientific expertise by the European Commission
- [ ] Divergent/conflicting economic interests between public and private parties
- [x] Other

* 5.51 Please specify

- Being asked to CE-mark under a system which is not yet built / unrealistic transition timelines: Logically, manufacturers should have been required to transition only once all required – even the minimal required – infrastructure was in place to enable their certification under MDR. There is a strong sense that manufacturers have been asked to transition to MDR while its transitional periods were fully taken up by an intense system construction, marked by very gradual designation of Notified Bodies and gradual appearance of infrastructure and guidance. The MDR transition periods have been repeatedly amended due to the scale of required changes. The gradual way in which the system has been implemented not only damaged trust of manufacturers in the regulatory system, it also damaged the implementation of the system itself. For

example, because Notified Bodies were designated slowly – and they themselves had to invest heavily in their designation – this contributed to higher costs being asked from manufacturers, challenging conditions being placed on manufacturers and considerably longer and unpredictable product assessment timelines – issues which continue to persist today despite higher numbers of Notified Bodies available.

• Captain of the ship – there are many bodies today which are part of governing the regulatory system yet there is no one body or part of the system which is accountable for ensuring that devices which meet their safety and performance claims can become available for health systems. For example during COVID it was unclear which body a manufacturer should turn to for regulatory decision on products to combat SARS-CoV-2. During implementation of MDR, the role of taking regulatory decisions – a role best held by an authority – has somewhat been left to Notified Bodies in many pre-market areas. Another issue is different national authority approaches including how different designating authorities manage Notified Bodies – leading to fragmentation of the single market on e.g., issues like applicability of Article 97 derogations, whether audits can be performed remotely and how individual Notified Bodies carry out their policies.

• MDCG guidance – MDCG guidance updates can contribute to clarity and good implementation. The frequent updates may also have the effect of further undermining regulatory stability and trust. Not all Competent Authorities apply MDCG guidance in the same way and more use of implementing acts should be considered. The sheer volume of MDCG guidance could be reviewed and provided in a user-friendly and consistent manner. At the same time, MDCG guidance does not yet address – almost 8 years into the transition periods – burning needs for manufacturers such as how to achieve early clarity on clinical evidence (see next point), predictability in conformity assessment and change control, clarity on post-market surveillance system, and focus to use Notified Body resources better in the regulatory system.

• Need for clarity on clinical evidence – the inability to discuss clinical strategy with the Notified Body well before submitting the conformity assessment application can lead to significant rework of technical documentation on the part of the manufacturer and even to a need to start a fresh clinical investigation. In turn this can lead to significant and costly delays in the system.

• Eroding trust in the system: MDR impact on devices availability – both those on the market and new devices shifting away from Europe – has been noted by healthcare professionals and patients (ref: surveys by BioMedical Alliance Dec 2023 and European Patient Forum Dec 2024). It should be noted that criteria for device safety and performance, is the one area which is largely unchanged between the medical devices directives and MDR.

• Declining CE marking reliance: Non-EU countries that once depended mainly on CE marking are moving away, creating uncertainty about a device's lawful market status (e.g., Brazil did not include Europe to the list of jurisdictions of reference in the reliance pathway introduced last year (IN 290/2024) and countries such as UK, Switzerland and Australia are considering adding new reliance partners.

## MD - Functioning of the internal market

### 5.73 To what extent do you agree that the Regulation has contributed to:

| | Strongly disagree | Disagree | Neutral | Agree | Strongly agree | Not applicable/ I don't know |
|---|---|---|---|---|---|---|
| * rules being applied fairly and impartially to all stakeholders | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| **before** a device is CE-marked | ◉ | ○ | ○ | ○ | ○ | ○ |
| * 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 | ◉ | ○ | ○ | ○ | ○ | ○ |
| * The creation of an **equal playing field** for **health institutions** | ○ | ○ | ○ | ○ | ○ | ◉ |

* 5.74 What do you see as the most important barrier to applying rules fairly and impartially to all stakeholders before a device is CE-marked? Please select all that apply.

- [x] The ways of working between notified bodies, economic operators, competent authorities and the European Commission is inefficient
- [x] The tools and processes in the Regulations are not in place (e.g. EUDAMED, EU reference laboratories, coordinated assessment of clinical investigations and performance studies etc.)
- [x] Divergences in interpretation and application of the Regulation by competent authorities, European Commission and notified bodies
- [x] Lack of clarity on the legal requirements for stakeholders
- [x] The requirements in the Regulation are too burdensome
- [ ] Lack of resources (financial/human/technical)
- [ ] Lack of clinical and scientific expertise by economic operators
- [x] Lack of clinical and scientific expertise by notified bodies
- [x] Lack of clinical and scientific expertise by competent authorities
- [ ] Lack of clinical and scientific expertise by the European Commission
- [ ] Divergent/conflicting economic interests between public and private parties
- [x] Other

* 5.75 Please specify

Reasons are several including lack of a single accountable governance structure overseeing the regulatory system including Notified Bodies, the way in which the MDR was structured and implementation of EUDAMED.

Impacts

• The feasibility of conducting clinical investigations for medical devices varies by country due to significant differences in authorisation and notification requirements across the EU. There are also country specific portals and processes for applying for authorisation which can make conducting multi-country investigations challenging.
• Derogations to allow a device to market to address health needs, rarely are used. Competent Authorities may have few resources and in some cases may lack expertise to provide such authorisations. However, when derogations are provided, they will typically be provided in individual countries and almost never at EU level (in fact, this only happened once). This can disadvantage EU citizens and manufacturers equally, given that access is unequal.

Notified Bodies have significant differences in how they interpret:
• Device classification, e.g. rule 8 non-implantable accessories to implantable devices might be treated as class III devices by some Notified Bodies (based on their Competent Authority's interpretation) and not by others. This is connected to the misalignment between the MDR Annex VIII text and the MDCG Classification guidance (which indicates these accessories as class III in conflict to the classification rule on accessories). Rule 11 (Software) is also subject to different interpretations by Notified Bodies, whereby the same device might be class IIa or IIb depending on the Notified Body.
The classification of devices as WET (Well-Established Technologies) is determined by the Notified Body's decision, which is influenced by the stance of the Competent Authority and whether it accepts the definition of WET outlined in MDCG 2020-6.

• The sufficiency of clinical evidence for a specific device may be assessed differently by various NBs or even by different reviewers within the same Notified Body. In many cases, the clinical evidence requirements are disproportionate to the device's risk class and its established reputation, particularly for legacy devices not officially classified as WET in the MDR text.

• Pre-submission dialogue with NB – some offer it, some do not; 41% of respondents in the MedTech Europe 2024 survey said that pre-submission dialogue is available for their NB and 23% indicated their NB has not introduced any implementation supporting measures – this includes pre-submission dialogue. The detailed findings of this survey will be attached to the Call for Evidence.
The inability to discuss clinical strategy with the Notified Body well before submitting the conformity assessment application significantly worsens MDR implementation challenges. It is crucial for the manufacturer and Notified Body to align their expectations early in the process, as the reasons for this are outlined in our paper (the MedTech Europe's publication "Urgent call for clarity on clinical strategy discussions" can be found under the link mentioned in response to the Question 8.1)

Also:
• The European Union departs from the global IMDRF-approach being the only jurisdiction proposing to implement the Master UDI-DI as a regulatory solution. The regulatory concept of Master UDI-DI compromises logistical and supply chain processes, globally as the UDI-DI for devices with a high number of variants no longer identifies the type of device uniquely (but a group of devices).

• The EUDAMED database currently has many data attributes as non-updatable which would implicate the need of new UDI-DIs for certain scenarios. These changes lead to the assignment of a regional UDI-DI and as a consequence burden the supply chain and eventually users, overwhelm global registration, adding costs without adding value to users.

* 5.76 What do you see as the most important barrier to applying rules fairly and impartially to all stakeholders after a device is CE-marked? Please select all that apply.

- [x] The ways of working between notified bodies, economic operators, competent authorities and the European Commission is inefficient
- [x] The tools and processes in the Regulations are not in place (e.g. EUDAMED, EU reference laboratories, coordinated assessment of clinical investigations and performance studies etc.)
- [x] Divergences in interpretation and application of the Regulation by competent authorities, European Commission and notified bodies
- [x] Lack of clarity on the legal requirements for stakeholders
- [x] The requirements in the Regulation are too burdensome
- [ ] Lack of resources (financial/human/technical)
- [ ] Lack of clinical and scientific expertise by economic operators
- [ ] Lack of clinical and scientific expertise by notified bodies
- [ ] Lack of clinical and scientific expertise by competent authorities
- [ ] Lack of clinical and scientific expertise by the European Commission
- [ ] Divergent/conflicting economic interests between public and private parties
- [x] Other

* 5.77 Please specify

Reasons are several, including lack of a single accountable governance structure overseeing the regulatory system including Notified Bodies is lacking, the way in which the MDR was structured and Competent Authority practice.

Notified Bodies approach the change notification process, Periodic Safety Update Reports (PSURs), and vigilance reviews differently.

During the COVID-19 pandemic, Notified Bodies adopted varying approaches to conducting audits, with some permitting remote audits while others required on-site inspections. This inconsistency led to inefficiencies and a lack of clear direction for all market participants.

Art 10a) implementation - in the Netherlands, Competent Authorities have introduced fines for non-compliance with these obligations, even though such penalties are not specified in Article 10a. Additionally, the scope of data required to be published is extensive, exceeding the requirements outlined in MDR.

The process for obtaining a Certificate of Free Sale (CFS)is highly fragmented across EU Member States. The type of information required varies, costs differ, and in some countries, it is possible to request a CFS online, while in others, this option is not available. Having the EU adopting a Model for CFS (both electronically and in paper format, available in all EU languages) will increase acceptance of these documents in non-EU/non-EEA countries. Likewise, it remains important to explain that CFS may be issued by the competent authorities of all EU Member States and all have the same value, given the issues

encountered with the non-recognition of CFS issued by certain Member States in certain third countries (e. g., Israel, Pakistan). Last, it should be made possible to request CFS by entities placing systems and procedure packs on the market.

Lack of visibility over regulatory costs hits many but not all manufacturers. ~50% manufacturers have low visibility over next year's budget for certification and maintenance whereas ~30% say they have high visibility. This indicates that some but not all manufacturers are able to plan and provision for adequate financing for the MDR ("MedTech Europe 2024 Regulatory Survey: key findings and insights" can be found under the link mentioned in response to the Question 8.1).

* 5.78 What do you see as the most important barrier to the creation of an equal playing field for all economic operators (regardless of company size or market position)? Please select all that apply.

- [x] The ways of working between notified bodies, economic operators, competent authorities and the European Commission is inefficient
- [x] The tools and processes in the Regulations are not in place (e.g. EUDAMED, EU reference laboratories, coordinated assessment of clinical investigations and performance studies etc.)
- [x] Divergences in interpretation and application of the Regulation by competent authorities, European Commission and notified bodies
- [x] Lack of clarity on the legal requirements for stakeholders
- [x] The requirements in the Regulation are too burdensome
- [x] Lack of resources (financial/human/technical)
- [ ] Lack of clinical and scientific expertise by economic operators
- [ ] Lack of clinical and scientific expertise by notified bodies
- [ ] Lack of clinical and scientific expertise by competent authorities
- [ ] Lack of clinical and scientific expertise by the European Commission
- [ ] Divergent/conflicting economic interests between public and private parties
- [x] Other

* 5.79 Please specify

A single accountable governance structure overseeing the regulatory system including Notified Bodies is needed to ensure a level playing field for all economic operators. A system for redress also is needed. Differences between national interpretation should be removed as far as possible.

Predictable and transparent timelines and costs are needed for all processes required for CE-marking and maintaining the device on the EU market. All such processes should be clear and user-friendly to access and use so that any company is able to engage in them regardless of company size.

Examples of barriers (past and present):

1) During the COVID pandemic, some Notified Bodies were permitted to conduct remote audits whereas

others were not.
2) Some Competent Authorities (and the Notified Bodies themselves) have been more supportive of their Notified Body conducting structured dialogues.
3) In the lead up to the 2nd extension of the MDR transitional provisions, some Competent Authorities issued Art. 97 derogations whereas others did not.
4) The amount of documentation which needs to be produced for compliance with MDR requirements compared to the directives have increased significantly, much of which is considered a purely administrative exercise. Having to comply with the new requirements can be challenging for large companies but it might be a dealbreaker for SMEs and start-ups.
5) SMEs have had a more difficult time finding a Notified Body (as indicated in MedTech Europe's MDR survey report of 2022 which can be found under the link mentioned in response to the Question 8.1) and faced a number of other difficulties (e.g. finding regulatory employees as revealed by MedTech Europe's 2024 the link of which you can find under the Question 8.1).
6) System and Procedure Pack Producers (SPPPs) cannot obtain Certificate of Free Sale (FSC) for their systems and procure packs (SPPs). This is only possible for manufacturers and Authorised Representatives per MDR Art.60. This situation leads to confusion and challenges for exporters. Because of this complication SPPs are being taken off markets.
7) Variations of Competent Authorities' requirements for importer verifications of products (just administrative or having to break down shipment boxes; level of details expected differs as well). Interpretations equally vary among Competent Authorities on who the importer is.

* 5.86 To what extent do you agree that guidance documents produced by the Medical Device Coordination Group overall enhance legal clarity on provisions of the Regulation?

- ○ Strongly disagree
- ◉ Disagree
- ○ Neutral
- ○ Agree
- ○ Strongly agree
- ○ Not applicable/ I don't know

## MD - Competitiveness and Innovation

5.87 To what extent do you agree that the Regulation has contributed to:

| | Strongly disagree | Disagree | Neutral | Agree | Strongly agree | Not applicable/ I don't know |
|---|---|---|---|---|---|---|
| * The **competitiveness** of the medical device sector in the EU? | ◉ | ○ | ○ | ○ | ○ | ○ |
| * **Innovation** in the medical device sector taking place in the EU? | ◉ | ○ | ○ | ○ | ○ | ○ |

* 5.88 What do you see as the most important barrier to the competitiveness of the medical device sector in the EU? Please select all that apply.

- [x] The ways of working between notified bodies, economic operators, competent authorities and the European Commission is inefficient
- [x] The tools and processes in the Regulations are not in place (e.g. EUDAMED, EU reference laboratories, coordinated assessment of clinical investigations and performance studies etc.)
- [x] Divergences in interpretation and application of the Regulation by competent authorities, European Commission and notified bodies
- [x] Lack of clarity on the legal requirements for stakeholders
- [x] The requirements in the Regulation are too burdensome
- [x] Lack of resources (financial/human/technical)
- [ ] Lack of clinical and scientific expertise by economic operators
- [ ] Lack of clinical and scientific expertise by notified bodies
- [x] Lack of clinical and scientific expertise by competent authorities
- [ ] Lack of clinical and scientific expertise by the European Commission
- [ ] Divergent/conflicting economic interests between public and private parties
- [x] Lack of support and incentives from the public sector
- [x] Lack of scientific and/or regulatory advice
- [x] Other

* 5.89 Please specify

All MDR challenges listed in questions above (administrative burden, inefficiency, fragmentation, excessive costs and timelines etc.) act as barriers to competitiveness. There is significant data to show that MDR is having an impact on innovation projects. For example, ~50% of MD manufacturers report a significant decline in new device development and 33% of large and 19% of smaller companies are moving their 1st regulatory launches outside of the EU.

The competitiveness of the wider industry and even the viability of many SMEs are at risk due to the high costs, high complexity, long timelines and uncertainty associated with CE-marking under MDR.

With regard to the competitiveness of the EU versus other jurisdictions, specifically, we would like to highlight that lack of clarity on the new requirements and timelines by non-EU/non-EEA authorities may lead to less trust and ultimately cause a barrier to competitiveness:

• The value of CE-marking is negatively impacted (e.g. Brazil that traditionally relied on CE mark, no longer does so)

• EU is not yet a full member of the Medical Device Single Audit Program (MDSAP) Regulatory Authority Council, which is gaining in importance (EU is acting as only an observer). The full membership of the EU to the MDSAP would reduce regulatory complexity, increase international regulatory harmonisation, and reduce

time to market by streamlined audits and foster competitiveness and innovation, especially for small and medium-sized enterprises (SMEs).

• Australia used to rely exclusively on EU in the past but now has enabled reliance on approvals from other comparable jurisdictions – this may lead to impacting competitiveness of EU products in Australia.

• Other jurisdictions that were traditionally tightly connected to the EU, while still relying on CE marking, also do seek other possibilities for reliance (e.g. Switzerland, UK).

* 5.90 What do you see as the most important barrier to innovation in the medical device sector in the EU? Please select all that apply.

- [x] The ways of working between notified bodies, economic operators, competent authorities and the European Commission is inefficient
- [x] The tools and processes in the Regulations are not in place (e.g. EUDAMED, EU reference laboratories, coordinated assessment of clinical investigations and performance studies etc.)
- [x] Divergences in interpretation and application of the Regulation by competent authorities, European Commission and notified bodies
- [x] Lack of clarity on the legal requirements for stakeholders
- [x] The requirements in the Regulation are too burdensome
- [x] Lack of resources (financial/human/technical)
- [ ] Lack of clinical and scientific expertise by economic operators
- [ ] Lack of clinical and scientific expertise by notified bodies
- [x] Lack of clinical and scientific expertise by competent authorities
- [x] Lack of clinical and scientific expertise by the European Commission
- [x] Divergent/conflicting economic interests between public and private parties
- [x] Lack of support and incentives from the public sector
- [x] Lack of scientific and/or regulatory advice
- [x] Other

* 5.91 Please specify

MedTech Europe considers that ‘innovation’ refers to breakthrough, disruptive medical technologies AS WELL AS iterative changes (device improvements) which enhance the functionality and performance of existing technologies, such as software updates, improved battery life, better interoperable services, and offering a technology used in a clinical setting for home or point of care use.

In general, a review of the regulatory framework is needed to identify how it can support bringing innovation in medical technologies to the EU market. The European Commission should adopt policies specifically aimed at better supporting innovation as part of its reforms of MDR, including ensuring a predictable and efficient processes for certification and assessment of new innovations and optimisation of existing

technologies.

Barriers today to innovation (list non-exhaustive):

- All MDR challenges listed in questions 5.15, 5.75, 5.77, 5.79 (admin burden, inefficiency, fragmentation, excessive costs and timelines etc.) act as barrier to innovation in the EU compared with other jurisdictions. The length, cost and unpredictability of conformity assessment, which act as deterrents for manufacturers and their investment in research and innovation, particularly if these elements are seen as significant business risks. Also, the timelines and cost for device optimisations (improvements; i.e. through change notification to the Notified Body) process are often unpredictable.

- Another significant barrier is equally the lack of swift and clear regulatory pathways for CE-marking breakthrough innovations and for specific device types such as orphan, niche and pediatric.

- Compared to the situation under the MD Directive, EU is now less attractive for the initial regulatory approval for first launches of new products. A decrease of 33% (large companies) and 19% (small companies) for the EU as choice for initial market is reported since the MDR date of application (see MedTech Europe 2024 regulatory survey report which can be found under the link mentioned in response to the Question 8.1).

- These, combined with the lack of an innovation pathway in the EU, represents a recognised challenge for industry with implications on the EU as the market of choice for first launches, in favor of other markets (e. g., USA). Innovation pathways are already present in for example, the USA, Japan, and China, while an increasing number of jurisdictions are considering developing their ones too (e.g., Brazil, Saudi Arabia, UK).

- All regulatory pathways (regardless of device type) should take a life-cycle approach into account and take sufficient regard to risk of the products as well as the processes. Ultimately, where the regulatory system does not work – innovation does not work. Manufacturers will bring their innovative solutions to a trusted, predictable and efficient regulatory system.

## MD - EU added value

* 5.96 To what extent do you agree that it is preferable to have one EU Regulation in this field instead of individual national regulations covering the same aspects?

- ○ Strongly disagree
- ○ Disagree
- ○ Neutral
- ◉ Agree
- ○ Strongly agree
- ○ Not applicable/ I don't know

## MD - Relevance and coherence of the EU rules on medical devices

5.97 To what extent do you agree that the Regulation addresses:

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | | Not applicable/ |

| | Strongly disagree | Disagree | Neutral | Agree | Strongly agree | I don't know |
|---|---|---|---|---|---|---|
| * Emerging health challenges and evolving patient needs | ○ | ◉ | ○ | ○ | ○ | ○ |
| * Emerging technological (including digital) or scientific progress in the sector | ○ | ○ | ◉ | ○ | ○ | ○ |
| * Potential future technological and scientific innovation in the sector (e.g. research and development) | ◉ | ○ | ○ | ○ | ○ | ○ |
| * Environmental sustainability | ○ | ◉ | ○ | ○ | ○ | ○ |
| * Cybersecurity | ○ | ○ | ○ | ◉ | ○ | ○ |

5.98 To what extent do you agree that the Regulation is coherent with other EU rules in the following fields:

| | Strongly disagree | Disagree | Neutral | Agree | Strongly agree | Not applicable/ I don't know |
|---|---|---|---|---|---|---|
| * Chemicals | ○ | ◉ | ○ | ○ | ○ | ○ |
| * Packaging and labelling | ○ | ◉ | ○ | ○ | ○ | ○ |
| * Ecodesign | ○ | ◉ | ○ | ○ | ○ | ○ |
| * Digital (e.g. AI Act 2024 /1689) | ○ | ◉ | ○ | ○ | ○ | ○ |
| * Cybersecurity (e.g. Directive (EU) 2022/2555) | ○ | ○ | ○ | ◉ | ○ | ○ |
| * Crisis management (e.g. Regulation (EU) 2022/123) | ◉ | ○ | ○ | ○ | ○ | ○ |
| * Products (e.g. Regulation (EU) 2023/1230) | ○ | ○ | ◉ | ○ | ○ | ○ |
| * Market surveillance (e.g. Regulation (EU) 2019/1020) | ○ | ○ | ◉ | ○ | ○ | ○ |
| * Medicinal products (e.g. Regulation (EU) 726/2004, Directive 2001/83/EC) | ○ | ○ | ◉ | ○ | ○ | ○ |

* 5.99 Is there another field of coherence of the MDR with other EU rules on which you would like to comment on?

◉ Yes

No

5.100 Please elaborate

MedTech Europe offers the following recommendations regarding legislations that require alignment with the MDR:

• Environment sustainability legislation - MedTech Europe sees the need for a structured alignment of compliance deadlines of any environment regulation with MDR specific regulatory system timelines. In particular, we recommend simplifying EU chemicals legislation, i.e. REACH Regulation (EU) 1907/2006, for any new restriction and authorisation of a substance used in a validated medical technology, the revised REACH Regulation should lay down a realistic and appropriate derogation period of at least 10 years for new products, which should also include their manufacturing processes, imports, and supply chain. New restrictions and authorisations should not apply on existing products already placed on the market. Options instead of restriction and derogation should also be considered where alternatives are not available and emissions/conditions are controlled. Additionally, the validity periods for RoHS Directive exemptions specific to medtech should also align with the MDR timelines. The MDR-specific guidance on "significant changes" should be reassessed to ensure it effectively supports innovation in sustainable materials.

• Circular Economy - MedTech Europe requests that the MDR should not inhibit the circularity of medical technologies.

The specificities of medical technologies and its regulatory system should also be better taken into account in other EU legislation, for example including (not exhaustive list):
• Batteries Regulation
• EU Deforestation Regulation
• Product liability Directive & AI liability Directive (multiple cross-references about provisions related to product safety and duty of care that are not clarified. Impact with regards to presumption of liability).
• EHDS
• GDPR (the MDR creates an overlap with the GDPR, particularly in areas like clinical investigations and post-market surveillance, where companies must comply with both regulations. However, the GDPR does not explicitly recognize MDR compliance as a legal basis for processing personal data, creating legal uncertainty.)
• General Product Safety Regulation (some medical devices could fall under the provisions of GPSR with regards to online marketplaces and the applicability of this regulation in general for devices is unclear).
• Rules for EU health emergencies (MDR derogations do not work)

Finally, with respect to question 5.101 we stress that MDR should continue to address device safety and performance. MDR does not, and should not, cover sustainable production methods, which are already regulated under other specific EU legislation, including IED, REACH, RoHS, EU water and other local permitting legislation.

* 5.101 To what extent do you agree that existing rules facilitate the development of **sustainable production methods**?

Strongly disagree
Disagree
Neutral

Agree

- Strongly agree
- Not applicable/ I don't know

5.102 To what extent do you agree that:

| | Strongly disagree | Disagree | Neutral | Agree | Strongly agree | Not applicable/ I don't know |
|---|---|---|---|---|---|---|
| * The provisions in the Regulation are coherent with one another | ○ | ◉ | ○ | ○ | ○ | ○ |
| * The provisions of the MDR are coherent with the provisions of the IVDR | ○ | ◉ | ○ | ○ | ○ | ○ |

* 5.103 Please explain by providing examples of where coherence within the Regulation is lacking.

MedTech Europe points out several specific examples:

• Preambles 1 and 2 state that one of the aims of the Regulation is to support innovation and SMEs. But there are no provisions for fostering innovation and supporting SMEs 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.

• Article 52 Conformity Assessment Procedures, requires devices which are sampled to follow section 4 of Annex IX. However in practice and according to MDCG 2019-13 (see section 5.2. Applicability of Chapter II, Section 4 of Annex IX) only Annex IX 4.1-4.18 are followed for such devices since no technical documentation assessment certificate is issued.

• There is an omission in the MDR legislation, whereby Article 60 only allows for CFS (Certificate of Free Sale) to be provided for CE Marked devices which then omits procedure packs per Article 22.1/22.3. System and Procedure Pack Producers (SPPPs) cannot obtain FSC for their systems and procure packs (SPPs) as this is only possible for manufacturers and Authorised Representatives per MDR Art.60. This causes many problems and leads to some procedure packs being taken off other markets as they cannot obtain a CFS.

• Annex VI, Part C, Point 6.3 per our reading should apply only to procedure packs as per Article.22.1 and 22.3 and not to Article 22.4, however, the point 6.3 heading currently says ‘’article 22’’ which is misleading.

• There is a discrepancy between MDR text, Annex VII, rule 8, (specifically impacting indent 6) and the MDCG Classification guidance. Rule 8 heading clearly applies to “all implantable and long term surgically invasive devices’’. The classification guidance classifies ‘non implantable’ accessories together with

implantable devices in class III contrary to what can be read in the legal text, causing an enormous amount of difficulties.

* 5.104 Please explain by providing examples of where coherence between the MDR and IVDR is lacking.

Please see the examples mentioned in the IVD section 6, see Question 6.97.

## MD - Efficiency of the EU rules on medical devices

When answering the following questions, please consider the following definitions.

**Compliance costs: the costs that need to be borne to comply with the provisions of the regulations.*

**Administrative costs: are part of compliance costs and are those costs borne by businesses, citizens, civil society organisations and public authorities as a result of administrative activities performed to comply with administrative obligations included in legal rules*

5.105 For the organisation you represent and based on your experience in the last 3 years, to what extent do you agree with the following:

**For phase 1**: 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

| | Strongly disagree | Disagree | Neutral | Agree | Strongly agree | Not applicable/ I don't know |
|---|---|---|---|---|---|---|
| * The costs for complying with the regulation with regards to the activities listed are acceptable | ◉ | ○ | ○ | ○ | ○ | ○ |
| * The administrative costs for the activities listed are acceptable | ◉ | ○ | ○ | ○ | ○ | ○ |
| * The costs for complying with the Regulation with regards to the activities listed will decrease once the Regulation is fully implemented | ◉ | ○ | ○ | ○ | ○ | ○ |
| * The administrative costs for the activities listed will | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| decrease once the Regulation is fully implemented | ◉ | ○ | ○ | ○ | ○ | ○ |

5.106 For the organisation you represent and based on your experience in the last 3 years, to what extent do you agree with the following:

**For phase 2:** 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

| | Strongly disagree | Disagree | Neutral | Agree | Strongly agree | Not applicable/ I don't know |
|---|---|---|---|---|---|---|
| * The costs for complying with the Regulation with regards to the activities listed are acceptable | ◉ | ○ | ○ | ○ | ○ | ○ |
| * The administrative costs for the activities listed are acceptable | ◉ | ○ | ○ | ○ | ○ | ○ |
| * The costs for complying with the Regulation with regards to the activities listed will decrease once the Regulation is fully implemented | ◉ | ○ | ○ | ○ | ○ | ○ |
| * The administrative costs for the activities listed will decrease once the Regulation is fully implemented | ◉ | ○ | ○ | ○ | ○ | ○ |

5.107 For the organisation you represent and based on your experience in the last 3 years, to what extent do you agree with the following:

**For phase 3:** activities for the compliance with post market obligations; activities related to vigilance; activities related to market surveillance

| | Strongly disagree | Disagree | Neutral | Agree | Strongly agree | Not applicable/ I don't know |
|---|---|---|---|---|---|---|

| | | | | | | |
|---|---|---|---|---|---|---|
| * The costs for complying with the Regulation with regards to the activities listed are acceptable | ◉ | ○ | ○ | ○ | ○ | ○ |
| * The administrative costs for the activities listed are acceptable | ◉ | ○ | ○ | ○ | ○ | ○ |
| * The costs for complying with the Regulation with regards to the activities listed will decrease once the Regulation is fully implemented | ◉ | ○ | ○ | ○ | ○ | ○ |
| * The administrative costs for the activities listed will decrease once the Regulation is fully implemented | ◉ | ○ | ○ | ○ | ○ | ○ |

5.108 For the organisation you represent and based on your experience in the last 3 years, to what extent do you agree with the following:

**For phase 4:** activities for providing information on devices or certificates; activities providing guidance to the sector

| | Strongly disagree | Disagree | Neutral | Agree | Strongly agree | Not applicable/ I don't know |
|---|---|---|---|---|---|---|
| * The costs for complying with the Regulation with regards to the activities listed are acceptable | ◉ | ○ | ○ | ○ | ○ | ○ |
| * The administrative costs for the activities listed are acceptable | ◉ | ○ | ○ | ○ | ○ | ○ |
| * The costs for complying with the Regulation with regards to the activities listed will decrease once the Regulation is fully implemented | ◉ | ○ | ○ | ○ | ○ | ○ |
| * The administrative costs for the activities listed will | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| decrease once the Regulation is fully implemented | ◉ | ○ | ○ | ○ | ○ | ○ |

*5.109 To what extent do you agree that complying with one Regulation on medical devices at EU level decreases the **compliance costs** for your or the organisation you represent, compared to having to comply with different set of rules on medical devices at national level ?

- ○ Strongly disagree
- ○ Disagree
- ○ Neutral
- ◉ Agree
- ○ Strongly agree
- ○ Not applicable/ I don't know

*5.110 To what extent do you agree that complying with one Regulation on medical devices at EU level decreases the **administrative costs** for your or the organisation you represent, compared to having to comply with different set of rules on medical devices at national level ?

- ○ Strongly disagree
- ○ Disagree
- ○ Neutral
- ◉ Agree
- ○ Strongly agree
- ○ Not applicable/ I don't know

*5.111 To what extent do you agree that it is feasible to maintain adequately safe devices on the EU market while reducing costs?

- ○ Strongly disagree
- ○ Disagree
- ○ Neutral
- ◉ Agree
- ○ Strongly agree
- ○ Not applicable/ I don't know

## 6 **Questions on** *in vitro* diagnostic medical devices (IVDR)

## IVD - Protection of health for patients and users

* 6.1 To what extend do you agree that the Regulation has contributed to protecting the health of **patients** in relation to medical devices?

- ○ Strongly disagree
- ○ Disagree
- ○ Neutral
- ○ Agree
- ○ Strongly agree
- ◉ Not applicable/ I don't know

* 6.2 To what extend do you agree that the Regulation has contributed to protecting the health of **users** in relation to medical devices?

*For the purpose of this question, 'users' are understood as any healthcare professional or lay person who uses a device.*

- ○ Strongly disagree
- ○ Disagree
- ○ Neutral
- ○ Agree
- ○ Strongly agree
- ◉ Not applicable/ I don't know

6.3 Based on the experience of the last 3 years, to what extent do you agree with the following:

| | Strongly disagree | Disagree | Neutral | Agree | Strongly agree |
|---|---|---|---|---|---|
| * The **performance** of CE-marked devices is good | ○ | ○ | ○ | ○ | ◉ |
| * The CE-marked devices are **safe** | ○ | ○ | ○ | ○ | ◉ |
| * There are robust **quality checks** before a device is placed on the market | ○ | ○ | ○ | ○ | ◉ |
| * Specific **patient needs are met** through the use of in-house and custom-made devices | ○ | ○ | ◉ | ○ | ○ |
| * **Safety issues** are adequately identified and addressed when detected | ○ | ○ | ○ | ○ | ◉ |
| * The sector and its industry is **duly regulated** | ◉ | ○ | ○ | ○ | ○ |

* 6.14 What do you think contributed to the sector not being duly regulated? Please select all that apply.

- [x] The ways of working between notified bodies, economic operators, competent authorities and the European Commission is inefficient
- [x] The tools and processes in the Regulations are not in place (e.g. EUDAMED, EU reference laboratories, coordinated assessment of clinical investigations and performance studies etc.)
- [x] Divergences in interpretation and application of the Regulation by competent authorities, European Commission and notified bodies
- [x] Lack of clarity on the legal requirements for stakeholders
- [x] The requirements in the Regulation are too burdensome
- [x] Lack of resources (financial/human/technical)
- [ ] Lack of clinical and scientific expertise by economic operators
- [ ] Lack of clinical and scientific expertise by notified bodies
- [x] Lack of clinical and scientific expertise by competent authorities
- [x] Lack of clinical and scientific expertise by the European Commission
- [ ] Divergent/conflicting economic interests between public and private parties
- [x] Other

* 6.15 Please specify

The structure and many elements of the IVDR in theory are fit for purpose for supporting it to achieve its objectives. However, both present, and absent elements of the legal text, the way in which the regulatory system has been implemented and ongoing infrastructure challenges are resulting in significant systemic deficiencies. While IVDR provides a good basis for device safety and performance, it falls short in fulfilling other objectives such as providing a robust and sustainable regulatory system which supports innovation and the industry, including the many SMEs active in the sector. For these reasons, MedTech Europe strongly disagrees that the regulatory system is duly regulated.

IVDR has expanded Notified Body oversight to 78% of IVDs, compared to only 8% under the previous IVD Directive. This overreach mirrors the MDR approach but applies a regulatory burden to many low-risk tests. IVDs present a different risk profile than medical devices, with most being low-risk and used under professional oversight in laboratories, which should be considered in the regulatory framework.

The risk-based approach mandated in the IVDR is not applied in practice as it fails to differentiate effectively between lower- and higher-risk devices. This creates significant challenges for manufacturers of lower-risk products. Additionally, many regulatory requirements, such as excessive sampling for low-risk devices (like the Class B) devices and burdensome regulations for low-risk studies (like studies requiring routine blood draws), add minimal value to patient safety or industry advancement.

The regulatory framework is unnecessarily complex and hence fails to help foster innovation, including device improvements and breakthrough technologies. Moreover, it does not adequately address the needs of SMEs, niche diagnostics, orphan IVDs, or AI-driven technologies. As a result, the system inhibits the

development and market entry of innovative IVD solutions, undermining progress in the sector.

The time-consuming certification process (up to 18 months), high regulatory costs, and complex administrative requirements create significant barriers for manufacturers. After 5 years of IVDR certification, manufacturers can face costs of around 2.9 million euros, prompting many to prioritize non-EU markets over the EU.

Key elements of the regulatory infrastructure, such as Common Specifications, Expert Panels, and EUDAMED, were either set up late or are still under development, causing delays and uncertainty for manufacturers.

The limited number and capacity of designated Notified Bodies, have caused delays in conformity assessments, impacting market access. Early-designated Notified Bodies gained an advantage, further complicating the situation.

The derogation mechanism outlined in Article 54 of the IVDR has never been used in practice, forcing companies to rely on national exemptions. This has resulted in fragmented regulatory responses, particularly during public health emergencies such as the COVID-19 pandemic. Despite the urgency, an EU-level derogation for IVDs was not implemented at a critical time.

The current governance framework requires a single, accountable structure. At the moment, the absence of a clear, responsible entity overseeing the system undermines competitiveness and hinders necessary course corrections. Additionally, the lack of effective mechanisms for allocating resources stifles innovation and limits the availability of IVDs.

The Regulation was intended to create a stable and finalised regulatory environment. In this ecosystem, manufacturers, patients and healthcare systems would rely on predictability and trust. Despite extending the transition periods, not all the issues that emerged during the implementation of the Regulation have been resolved, and problems remain. Furthermore, the lack of EUDAMED and other key elements has led to workarounds, creating uncertainty and adding unnecessary administrative burdens for all stakeholders involved.

* 6.17 To what extent do you agree that the extended transition periods of the Regulation have addressed concerns you/the members you represent had?

- ○ Strongly disagree
- ◉ Disagree
- ○ Neutral
- ○ Agree
- ○ Strongly agree
- ○ Not applicable/ I don't know

* 6.18 Please explain which concerns the extension of the transition periods did not address

The two sets of extended transitional periods have provided immediate relief to the system and helped keep legacy IVDs available. Legislators gave these extensions to ensure IVDs remain available to laboratories

and patients, as the common belief was that system readiness, including sufficient Notified Body capacity, was lacking.

The extensions ensured a greater availability of designated Notified Bodies before the deadlines of May 2024, but did not fully address capacity nor efficiency issues which persist in the Notified Bodies' system.

The extensions largely postponed but did not address major underlying systemic deficiencies which contributed to the need for extended transition time, including lack of system predictability, long conformity assessment timelines, high complexity in terms of requirements and high costs for gaining and maintaining CE-marking.

Despite a risk-based classification, the IVDR lacks a risk-based approach in its pre- and post-market requirements. Given that most IVDs in the EU are low-risk, class B devices with minimal patient contact and few incidents, the regulatory oversight is disproportionate to their risk profile. Moreover, unpredictable and excessive change notification requirements such as notification of non-significant or all device changes for Notified Body approval, double labelling updates and (re)registration costs, as well as access to updated devices. Disproportionately high requirements for class B devices, such as technical documentation sampling after the first certification cycle, considering the lower risk posed by those devices and lack of contact to the patient. The resources of the Notified Body system would be better spent with higher-risk devices or with class B devices where there is concern arising post-market.

IVDR certification and maintenance have become unsustainable for IVD manufacturers, especially SMEs, due to unpredictable timelines and high regulatory costs. These costs have doubled (or more) compared to the IVD Directive, largely due to administrative burdens. Reducing these burdens and applying a more risk-based approach is needed, as simply increasing implementation won't address the underlying issues.

Outside the EU jurisdiction, the degree of reliance on CE marking varies among countries. In the past, when fewer countries had a dedicated regulatory framework for medical devices, CE marking was considered a prerequisite for market access in those countries and this status provided benefits for EU-based exporters.

Over time, reliance on CE marking has started to weaken. A lower degree or even lack of CE marking recognition is being observed in several countries. This trend is partially attributed to the reform of the EU legislation brought by the IVDR. The complexity of changes and the transition, which is still underway and not tracking the original anticipated timeline, have resulted in confusion and distrust among non-EU regulators. A series of questions and issues which impact product registrations in third countries while leveraging CE certificates has arisen. As a result, industry is concerned that the CE marking as evidence of regulatory compliance under EU IVDR has lost much of its international credibility. For example, Brazil has introduced last year (IN 290/2024) a reliance pathway where market authorisation certificates from the 'Equivalent Foreign Regulatory Authorities' (US, Canada, Japan, and Australia – all full members of the Medical Device Single Audit Program, MDSAP) are accepted for expedited review for market authorisation (registration) in Brazil for certain medical devices. At the moment, this process does not include CE marking, even though, according to April 2024 data from ANVISA (the Brazilian Health Regulatory Agency), European products represent the largest percentage of medical devices of foreign origin in Brazil.

In order to restore trust in CE marking, an active, frequent presence of the European Commission in international fora and engagement in bilateral exchanges with other regulatory authorities would critically contribute to raise awareness about the latest development in the European regulatory framework for medical technologies. The large number of attendees to the info session for non-EU/non-EEA stakeholders on 04 July 2024 (800+) is a clear indicator of the high degree of interest of international stakeholders in the evolving EU regulatory framework. In doing so, communication should be more timely.

Today's regulatory system is burdened by complexity, inefficiency, inconsistent interpretation among Competent Authorities (CAs) and Notified Bodies, redundant requirements, and a lack of predictability regarding fees, timelines, and processes. Without addressing these fundamental issues, extensions merely delay the negative consequences rather than resolving them.

## IVD - Transparency and traceability

For the purpose of answering questions in this survey, please note that the terminology used in this section should be understood as follows:

**Transparency:** information about devices that are on the EU market (includes data regarding characteristics, the clinical data and the conformity assessment path of certain devices),

**Traceability:** the ability to precisely identify and track a specific medical device on the EU market.

6.45 Based on the experience of the last 3 years, to what extent do you agree that the regulation has contributed to achieving:

| | Strongly disagree | Disagree | Neutral | Agree | Strongly agree | Not applicable/ I don't know |
|---|---|---|---|---|---|---|
| * **transparency** of information on devices in the EU | ◉ | ○ | ○ | ○ | ○ | ○ |
| * **traceability** of devices in the EU | ◉ | ○ | ○ | ○ | ○ | ○ |
| * **trust** in the regulatory system of medical devices | ◉ | ○ | ○ | ○ | ○ | ○ |

* 6.46 What do you see as the most important barrier to the transparency of information on devices in the EU? Please select all that apply.

- [x] The ways of working between notified bodies, economic operators, competent authorities and the European Commission is inefficient
- [x] The tools and processes in the Regulations are not in place (e.g. EUDAMED, EU reference laboratories, coordinated assessment of clinical investigations and performance studies etc.)
- [x] Divergences in interpretation and application of the Regulation by competent authorities, European Commission and notified bodies
- [x] Lack of clarity on the legal requirements for stakeholders
- [ ] The requirements in the Regulation are too burdensome
- [ ] Lack of resources (financial/human/technical)
- [ ] Lack of clinical and scientific expertise by economic operators

- [ ] Lack of clinical and scientific expertise by notified bodies
- [ ] Lack of clinical and scientific expertise by competent authorities
- [ ] Lack of clinical and scientific expertise by the European Commission
- [ ] Divergent/conflicting economic interests between public and private parties
- [x] Other

*6.47 Please specify

The biggest barrier to transparency is the absence of a fully operational EUDAMED database: it is neither legally applicable nor fully populated. Beyond the availability of a mandatory database, there are issues with the development and efficiency of EUDAMED which will hamper transparency of information for all actors and stakeholders.

Inefficiency in collaboration and communication with stakeholders:
o EUDAMED is being developed without closely monitoring the needs of economic operators and Notified Bodies, despite them being responsible for submitting and maintaining the vast majority of the required data. Additionally, insufficient investment has gone into considering user needs—such as those of hospitals, healthcare professionals and patients.
o Economic operators hesitate to submit device information before the legal deadlines due to uncertainty about data update rules and mechanisms – and the possibility that incorrect submissions could trigger need for new UDI-DI. The lack of a correction function and limited discard option (only available before a certificate or vigilance case is linked) further complicates compliance. Moreover, the technical documentation and specifications provided are not yet qualified as sufficient for EUDAMED implementation, raising concerns about data quality.

Divergences in regulatory interpretation and application:
o There are inconsistencies in how the Summary of Safety and Performance (SSP) is handled, particularly regarding who is responsible for uploading it to EUDAMED (Notified Body or manufacturer?) and whether a patient section is required.
o EUDAMED demands information beyond legal requirements, including the registration of non-reportable devices (NRD), legacy devices, extensive data for Performance Study (PS) applications, and excessive details in the Manufacturer Incident Reporting form.

Future considerations:
o Shifting EUDAMED timelines have led to resource shortages within the industry, particularly affecting smaller companies by creating uncertainty about when major IT projects should be scheduled.
o EUDAMED requirements are anticipated to be burdensome (manual processes, increased number of data elements, minimal viable product approach).

*6.48 What do you see as the most important barrier affecting the traceability of devices in the EU? Please select all that apply.

- [x] The ways of working between notified bodies, economic operators, competent authorities and the European Commission is inefficient
- [x]

- [ ] The tools and processes in the Regulations are not in place (e.g. EUDAMED, EU reference laboratories, coordinated assessment of clinical investigations and performance studies etc.)
- [x] Divergences in interpretation and application of the Regulation by competent authorities, European Commission and notified bodies
- [x] Lack of clarity on the legal requirements for stakeholders
- [ ] The requirements in the Regulation are too burdensome
- [ ] Lack of resources (financial/human/technical)
- [ ] Lack of clinical and scientific expertise by economic operators
- [ ] Lack of clinical and scientific expertise by notified bodies
- [ ] Lack of clinical and scientific expertise by competent authorities
- [ ] Lack of clinical and scientific expertise by the European Commission
- [ ] Divergent/conflicting economic interests between public and private parties
- [x] Other

*6.49 Please specify

The identification of the device in the supply chain (traceability) is ensured through the storage of the UDI by economic operators (and by health institutions and health professionals). Traceability is not a new concept, it is applied by manufacturers for decades. This area is new for health institutions, as they must now retain and store UDI information (UDI-DI and UDI-PI) under national laws implementing the IVDR such as in Belgium and in Italy.
Note: tracking that is included in the explanation of traceability for this question is different.

Inefficiency in collaboration and communication / missing tools:

- There is no functionality yet implemented for mass data downloads of up-to-date device information from EUDAMED, limiting access for users, including laboratories and hospitals to UDI and device data.
- EUDAMED has built-in constraints that hinder the efficient management of mergers and acquisitions. It does not allow for the transfer of devices to a new legal entity, preventing the proper maintenance of traceability and vigilance history.

Divergences in regulatory interpretation and application:

- A significant number of device registration elements in EUDAMED are non-updatable: they cannot be changed without assigning a new device identifier (UDI-DI). This forces manufacturers to create a new UDI-DI and register a "new" device in EUDAMED when errors of the submitted device information are identified or when valid business events occur, such as change of Notified Body. This leads to multiple records for the same device in the database, undermining vigilance history.

Requirements too burdensome:

- Due to the lack of technological solutions such as “scanned as delivered” at hospitals and laboratories, users request UDI-DI/PI information via alternative means (e.g., shipping papers, emails). At the same time, manufacturers remain compliant with regulatory requirements by labelling their products with UDI-DI and UDI-PI accordingly.

* 6.50 What do you see as the most important barrier to building trust in the regulatory system of medical devices in the EU? Please select all that apply.

- [x] The ways of working between notified bodies, economic operators, competent authorities and the European Commission is inefficient
- [x] The tools and processes in the Regulations are not in place (e.g. EUDAMED, EU reference laboratories, coordinated assessment of clinical investigations and performance studies etc.)
- [x] Divergences in interpretation and application of the Regulation by competent authorities, European Commission and notified bodies
- [ ] Lack of clarity on the legal requirements for stakeholders
- [x] The requirements in the Regulation are too burdensome
- [ ] Lack of resources (financial/human/technical)
- [ ] Lack of clinical and scientific expertise by economic operators
- [ ] Lack of clinical and scientific expertise by notified bodies
- [ ] Lack of clinical and scientific expertise by competent authorities
- [ ] Lack of clinical and scientific expertise by the European Commission
- [ ] Divergent/conflicting economic interests between public and private parties
- [x] Other

* 6.51 Please specify

• Being asked to CE-mark under a system which is not yet built / unrealistic transition timelines: Logically, manufacturers should have been required to transition only once all required – even the minimal required – when the infrastructure was in place to enable their certification under IVDR. There is a strong sense that manufacturers have been asked to transition to IVDR while its transitional periods were fully taken up by an intense system construction, marked by very gradual designation of Notified Bodies and gradual appearance of infrastructure and guidance. For Class D devices, the elements needed for their conformity assessment arrived late in the transition, including the expert panel, EU Reference Laboratories and common specifications; this greatly increased uncertainty. EUDAMED is yet to become fully operational. The IVDR transition periods have been repeatedly amended due to the scale of required changes and lack of infrastructure. The gradual way in which the system was implemented not only damaged trust of manufacturers in the regulatory system, it also affected the implementation of the system itself. For example, because Notified Bodies were designated so slowly and in few numbers – and they themselves had to invest heavily in their designation – this contributed to higher costs being asked from manufacturers, challenging conditions being placed on manufacturers and considerably longer / unpredictable product assessment timelines – issues which continue to persist today despite the higher numbers of Notified Bodies available.

• Captain of the ship – there are many bodies today which are part of governing the regulatory system yet there is no one body or part of the system which is accountable for ensuring that devices which meet their safety and performance claims can become available for health systems. For example, during COVID it was unclear which body a manufacturer should turn to for regulatory decision on tests detecting exposure to, or presence of, SARS-CoV-2. During implementation of IVDR, the role of taking regulatory decisions – a role best held by an authority – has somewhat been relegated to Notified Bodies in many pre-market areas.

Another issue is the varying approaches taken by national authorities, particularly in how different designating bodies manage Notified Bodies. This leads to fragmentation within the single market on matters such as the applicability of Article 54 derogations, the possibility of remote audits, and the overall policies implemented by individual Notified Bodies.

• MDCG guidance – MDCG guidance updates can contribute to clarity and good implementation. Frequent updates may also have the effect of further undermining regulatory stability and trust. Not all Competent Authorities apply MDCG guidance in the same way and more use of implementing acts should be considered. The sheer volume of MDCG guidance could be reviewed and provided in a user-friendly and consistent manner. At the same time, MDCG guidance does not yet address – almost 8 years into the transition periods – burning needs for manufacturers such as how to achieve early clarity on clinical evidence (see next point), predictability in conformity assessment and change control, clarity on post-market surveillance system, and focus for using Notified Body resources better in the regulatory system.

• Need for clarity on clinical evidence – The inability to discuss clinical strategy with the Notified Body well before submitting the conformity assessment application can lead to significant rework of technical documentation on the part of the manufacturer and even to a need to start fresh collection of clinical evidence. In turn this can lead to costly delays in the system.

• Declining CE marking reliance: Non-EU countries that once depended mainly on CE marking are moving away, creating uncertainty about a device's lawful market status (e.g., Brazil did not include Europe to the list of jurisdictions of reference in the reliance pathway introduced last year (IN 290/2024) and countries such as UK, Switzerland and Australia are considering adding new reliance partners.

## IVD - Functioning of the internal market

### 6.68 To what extent do you agree that the Regulation has contributed to:

| | Strongly disagree | Disagree | Neutral | Agree | Strongly agree | Not applicable/ I don't know |
|---|---|---|---|---|---|---|
| * rules being applied fairly and impartially to all stakeholders **before** a device is CE-marked | ○ | ◉ | ○ | ○ | ○ | ○ |
| * 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 | ○ | ◉ | ○ | ○ | ○ | ○ |
| * The creation of an **equal playing field** for **health institutions** | ○ | ○ | ○ | ○ | ○ | ◉ |

* 6.69 What do you see as the most important barrier to applying rules fairly and impartially to all stakeholders before a device is CE-marked? Please select all that apply.

- [x] The ways of working between notified bodies, economic operators, competent authorities and the European Commission is inefficient
- [x] The tools and processes in the Regulations are not in place (e.g. EUDAMED, EU reference laboratories, coordinated assessment of clinical investigations and performance studies etc.)
- [x] Divergences in interpretation and application of the Regulation by competent authorities, European Commission and notified bodies
- [x] Lack of clarity on the legal requirements for stakeholders
- [x] The requirements in the Regulation are too burdensome
- [ ] Lack of resources (financial/human/technical)
- [ ] Lack of clinical and scientific expertise by economic operators
- [ ] Lack of clinical and scientific expertise by notified bodies
- [ ] Lack of clinical and scientific expertise by competent authorities
- [ ] Lack of clinical and scientific expertise by the European Commission
- [ ] Divergent/conflicting economic interests between public and private parties
- [x] Other

* 6.70 Please specify

Reasons are several including lack of a single accountable governance structure overseeing the regulatory system including Notified Bodies, the way in which the IVDR was structured and implementation of EUDAMED.

Impacts include:

- The feasibility of conducting performance studies varies by country due to significant differences in authorisation and notification requirements across the EU. There are also country specific portals and processes for applying for authorisation which can make conducting multi-country studies challenging. Performance studies combined with clinical trials currently are even more challenging caught as they are between two sets of requirements and an excessively fragmented performance studies authorisation process.
- Derogations to allow a device to market to address health needs, rarely are used. Competent Authorities may have few resources and in some cases may lack expertise to provide such authorisations. However, when derogations are provided, they will typically be provided in individual countries and have never been provided at EU level. This can disadvantage EU citizens and manufacturers, given that access is unequal.

Notified Bodies have significant differences in how they interpret:

- The sufficiency of clinical evidence for a specific device may be assessed differently by various Notified Bodies or even by different reviewers within the same Notified Body. In many cases, the clinical evidence requirements are disproportionate to the device's risk class and whether the device is in routine

clinical diagnostic use.

• Pre-submission dialogue with Notified Bodies – some offer it, some do not; The inability to discuss clinical strategy with the Notified Body well before submitting the conformity assessment application significantly worsens IVDR implementation challenges. It is crucial for the manufacturer and Notified Body to align their expectations early in the process, as the reasons for this are outlined in our paper (MedTech Europe position paper on 'Urgent call for clarity on clinical strategy discussions' can be found under the link mentioned in response to the Question 8.1)

Other:

• The EUDAMED database currently has many data attributes as non-updatable which would implicate the need of new UDI-DIs for certain scenarios. These changes lead to the assignment of a regional UDI-DI and as a consequence to burden to the supply chain and eventually to users, to global registration, to additional costs without any added value.

* 6.71 What do you see as the most important barrier to applying rules fairly and impartially to all stakeholders after a device is CE-marked? Please select all that apply.

- [x] The ways of working between notified bodies, economic operators, competent authorities and the European Commission is inefficient
- [x] The tools and processes in the Regulations are not in place (e.g. EUDAMED, EU reference laboratories, coordinated assessment of clinical investigations and performance studies etc.)
- [x] Divergences in interpretation and application of the Regulation by competent authorities, European Commission and notified bodies
- [x] Lack of clarity on the legal requirements for stakeholders
- [x] The requirements in the Regulation are too burdensome
- [ ] Lack of resources (financial/human/technical)
- [ ] Lack of clinical and scientific expertise by economic operators
- [ ] Lack of clinical and scientific expertise by notified bodies
- [ ] Lack of clinical and scientific expertise by competent authorities
- [ ] Lack of clinical and scientific expertise by the European Commission
- [ ] Divergent/conflicting economic interests between public and private parties
- [x] Other

* 6.72 Please specify

Reasons are several including lack of a single accountable governance structure overseeing the regulatory system including Notified Bodies is lacking, the way in which the IVDR was structured and Competent Authority practice.

• Notified Bodies have different interpretations for the change notification process, Periodic Safety

Update Reports (PSURs), and vigilance reviews.

• During the COVID-19 pandemic, Notified Bodies adopted varying approaches to conducting audits, with some permitting remote audits while others required on-site inspections. This inconsistency led to inefficiencies and a lack of clear direction for all market participants.

• Art 10a) implementation – some Competent Authorities have introduced fines for non-compliance with these obligations, even though such penalties are not specified in Article 10a. Additionally, the scope of data required to be published is extensive, exceeding the requirements outlined in IVDR.

• The process for obtaining a Certificate of Free Sale (CFS) is highly fragmented across EU Member States. The type of information required varies, costs differ, and in some countries, it is possible to request a CFS online, while in others, this option is not available. Having the EU adopting a Model for CFS (both electronically and in paper format, available in all EU languages) will increase acceptance of these documents in non-EU/non-EEA countries. Likewise, it remains important to explain that CFS may be issued by the competent authorities of all EU Member States and all have the same value, given the issues encountered with the non-recognition of CFS issued by certain Member States in certain third countries (e. g., Israel, Pakistan). Last, it should be made possible to request CFS by entities placing systems and procedure packs on the market.

• Lack of visibility over regulatory costs hits many but not all manufacturers. ~50% manufacturers have low visibility over next year's budget for certification and maintenance whereas ~30% say they have high visibility. This indicates that some but not all manufacturers are able to plan and provision for adequate financing for the IVDR. (see MedTech Europe 2024 regulatory survey report which can be found under the link mentioned in response to the Question 8.1).

* 6.73 What do you see as the most important barrier to the creation of an equal playing field for all economic operators (regardless of company size or market position)? Please select all that apply.

- [x] The ways of working between notified bodies, economic operators, competent authorities and the European Commission is inefficient
- [x] The tools and processes in the Regulations are not in place (e.g. EUDAMED, EU reference laboratories, coordinated assessment of clinical investigations and performance studies etc.)
- [x] Divergences in interpretation and application of the Regulation by competent authorities, European Commission and notified bodies
- [x] Lack of clarity on the legal requirements for stakeholders
- [x] The requirements in the Regulation are too burdensome
- [x] Lack of resources (financial/human/technical)
- [ ] Lack of clinical and scientific expertise by economic operators
- [ ] Lack of clinical and scientific expertise by notified bodies
- [ ] Lack of clinical and scientific expertise by competent authorities
- [ ] Lack of clinical and scientific expertise by the European Commission

- [ ] Divergent/conflicting economic interests between public and private parties
- [x] Other

*6.74 Please specify

A single accountable governance structure overseeing the regulatory system including Notified Bodies is needed to ensure a level playing field for all economic operators. A system for redress also is needed. Differences between national interpretation should be removed as far as possible.

Predictable and transparent timelines and costs are needed for all processes required for CE-marking and maintaining the device on the EU market. All such processes should be clear and user-friendly to access and use so that any size of company is able to engage in them.

Examples of barriers (past and present):

1) The amount of documentation which needs to be produced for compliance with IVDR requirements compared to the IVD Directive has increased significantly in the legal text and also through guidance and interpretation, some of which can be considered a purely administrative exercise especially where it is duplicative or not based on risk. Having to comply with the new requirements is difficult for large companies and might be a dealbreaker for SMEs and start-ups.

2) During the initial transition period of 5 years before application of IVDR, there were very few Notified Bodies designated under IVDR. Companies who already had a relationship with one of the few designated Notified Bodies had an advantage over other companies. Notified Bodies for certain countries and languages happened to be designated earlier than for others (e.g. France, Spain, Italy).

3) SMEs have had a more difficult time finding a Notified Body (as indicated by the results of the MedTech Europe IVDR survey report of 2022 which can be found under the link mentioned in response to the Question 8.1) and faced a number of other difficulties (e.g. finding regulatory employees as revealed by MedTech Europe 2024 regulatory survey report which can be found under the link mentioned in response to the Question 8.1).

4) Variations of Competent Authorities' requirements for importer verifications of products (just administrative or having to break down shipment boxes; level of details expected differs as well). Interpretations equally vary among Competent Authorities on who the importer is.

*6.81 To what extent do you agree that guidance documents produced by the Medical Device Coordination Group overall enhance legal clarity on provisions of the Regulation?

- ( ) Strongly disagree
- ( ) Disagree
- (•) Neutral
- ( ) Agree
- ( ) Strongly agree
- ( ) Not applicable/ I don't know

## IVD - Competitiveness and Innovation

6.82 To what extent do you agree that the Regulation has contributed to:

| | Strongly disagree | Disagree | Neutral | Agree | Strongly agree | Not applicable/ I don't know |
|---|---|---|---|---|---|---|
| * The **competitiveness** of the medical device sector in the EU? | ◉ | ○ | ○ | ○ | ○ | ○ |
| * **Innovation** in the medical device sector taking place in the EU? | ◉ | ○ | ○ | ○ | ○ | ○ |

* 6.83 What do you see as the most important barrier to the competitiveness of the medical device sector in the EU? Please select all that apply.

- ☑ The ways of working between notified bodies, economic operators, competent authorities and the European Commission is inefficient
- ☑ The tools and processes in the Regulations are not in place (e.g. EUDAMED, EU reference laboratories, coordinated assessment of clinical investigations and performance studies etc.)
- ☑ Divergences in interpretation and application of the Regulation by competent authorities, European Commission and notified bodies
- ☑ Lack of clarity on the legal requirements for stakeholders
- ☑ The requirements in the Regulation are too burdensome
- ☑ Lack of resources (financial/human/technical)
- ☐ Lack of clinical and scientific expertise by economic operators
- ☐ Lack of clinical and scientific expertise by notified bodies
- ☑ Lack of clinical and scientific expertise by competent authorities
- ☑ Lack of clinical and scientific expertise by the European Commission
- ☐ Divergent/conflicting economic interests between public and private parties
- ☐ Lack of support and incentives from the public sector
- ☑ Lack of scientific and/or regulatory advice
- ☑ Other

* 6.84 Please specify

All IVDR challenges listed in previous questions (administrative burden, inefficiency, fragmentation, excessive costs and timelines…) act as barriers to competitiveness. There is significant data to show that IVDR is having an impact on innovation projects.

The competitiveness of the wider industry and even the viability of many small businesses (SMEs) are at risk due to the high costs, high complexity, long timelines and uncertainty associated with CE-marking under IVDR.

With regard to the competitiveness of the EU vs other jurisdictions, specifically, we would like to highlight that lack of clarity on the new requirements and timelines by non-EU/non-EEA authorities may lead to less trust and ultimately cause a barrier to competitiveness:

- The value of CE-marking is negatively impacted (e.g. Brazil that traditionally relied on CE mark, no longer does so).

- EU is not yet a full member of the Medical Device Single Audit Program (MDSAP) Regulatory Authority Council, which is gaining in importance (EU is acting as only an observer). It would reduce regulatory complexity, increase international regulatory harmonisation, and reduce time to market by streamlined audits and foster competitiveness and innovation, especially for small and medium-sized enterprises (SMEs).

- Australia used to rely exclusively on EU in the past, but now has enabled reliance on approvals from other comparable jurisdictions – this may lead to impacting competitiveness of EU products in Australia.

- Other jurisdictions that were traditionally tightly connected to the EU, while still relying on CE marking, also do seek other possibilities for reliance (e.g. Switzerland, UK).

* 6.85 What do you see as the most important barrier to innovation in the medical device sector in the EU? Please select all that apply.

- [x] The ways of working between notified bodies, economic operators, competent authorities and the European Commission is inefficient
- [x] The tools and processes in the Regulations are not in place (e.g. EUDAMED, EU reference laboratories, coordinated assessment of clinical investigations and performance studies etc.)
- [x] Divergences in interpretation and application of the Regulation by competent authorities, European Commission and notified bodies
- [x] Lack of clarity on the legal requirements for stakeholders
- [x] The requirements in the Regulation are too burdensome
- [x] Lack of resources (financial/human/technical)
- [ ] Lack of clinical and scientific expertise by economic operators
- [ ] Lack of clinical and scientific expertise by notified bodies
- [x] Lack of clinical and scientific expertise by competent authorities
- [x] Lack of clinical and scientific expertise by the European Commission
- [x] Divergent/conflicting economic interests between public and private parties
- [x] Lack of support and incentives from the public sector
- [x] Lack of scientific and/or regulatory advice

☑ Other

*6.86 Please specify

All IVDR challenges listed in the previous questions (admin burden, inefficiency, fragmentation, excessive costs and timelines…) act as barrier to innovation in the EU compared with other jurisdictions.

The length, cost and unpredictability of conformity assessment, act as deterrents for manufacturers and their investment in research and innovation, particularly if these elements are seen as significant business risks. Also the timelines and cost for device optimisations (improvements; i.e. through change notification to the Notified Body) process are often unpredictable. The result is that many devices on the market today, as well as new, innovative medical technologies, are not reaching patients in Europe as they should. The regulatory framework must adopt policies specifically aimed at better supporting innovation as part of its broader reform, including ensuring a predictable and efficient process for certification of innovations and optimisation of existing technologies.

These, combined with the lack of an innovation pathway in the EU, represents a recognised challenge for industry with implications on the EU as the market of choice for first launches, in favor of other markets (e.g., USA). Innovation pathways are already present in for example the USA, Japan, China and Korea while an increasing number of jurisdictions are considering developing their ones too (e.g., Brazil, Saudi Arabia, UK).

Compared to the situation under the IVD Directive, EU is now less attractive for the initial regulatory approval for first launches of new products. A decrease of 40% (large companies) and 12% (small and medium sized companies) for the EU as choice for initial market is reported since the IVDR date of application (see MedTech Europe 2024 regulatory survey report which can be found under the link mentioned in response to the Question 8.1).

Another significant barrier is the lack of swift and clear regulatory pathways for CE-marking breakthrough innovations and for specific device types such as orphan (or rare diagnostics), niche and pediatric.

All regulatory pathways (regardless of device type) should take a life-cycle approach into account and take sufficient regard to risk of the products as well as the processes. Ultimately, where the regulatory system does not work – innovation does not work. Manufacturers will bring their innovative solutions to a trusted, predictable and efficient regulatory system.

## IVD - EU added value

*6.91 To what extent do you agree that it is preferable to have one EU Regulation in this field instead of individual national regulations covering the same aspects?

- ○ Strongly disagree
- ○ Disagree
- ○ Neutral
- ○ Agree
- ◉ Strongly agree
- ○ Not applicable/ I don't know

## IVD - Relevance and coherence of the EU rules on medical devices

6.92 To what extent do you agree that the Regulation addresses:

| | Strongly disagree | Disagree | Neutral | Agree | Strongly agree | Not applicable/ I don't know |
|---|---|---|---|---|---|---|
| * Emerging health challenges and evolving patient needs | ◉ | ○ | ○ | ○ | ○ | ○ |
| * Emerging technological (including digital) or scientific progress in the sector | ○ | ○ | ◉ | ○ | ○ | ○ |
| * Potential future technological and scientific innovation in the sector (e.g. research and development) | ◉ | ○ | ○ | ○ | ○ | ○ |
| * Environmental sustainability | ○ | ◉ | ○ | ○ | ○ | ○ |
| * Cybersecurity | ○ | ○ | ○ | ◉ | ○ | ○ |

6.93 To what extent do you agree that the Regulation is coherent with other EU rules in the following fields:

| | Strongly disagree | Disagree | Neutral | Agree | Strongly agree | Not applicable/ I don't know |
|---|---|---|---|---|---|---|
| * Chemicals | ○ | ◉ | ○ | ○ | ○ | ○ |
| * Packaging and labelling | ○ | ◉ | ○ | ○ | ○ | ○ |
| * Ecodesign | ○ | ◉ | ○ | ○ | ○ | ○ |
| * Digital (e.g. AI Act 2024 /1689) | ○ | ◉ | ○ | ○ | ○ | ○ |
| * Cybersecurity (e.g. Directive (EU) 2022/2555) | ○ | ○ | ○ | ◉ | ○ | ○ |
| * Crisis management (e.g. Regulation (EU) 2022/123) | ◉ | ○ | ○ | ○ | ○ | ○ |
| * Products (e.g. Regulation (EU) 2023/1230) | ○ | ○ | ◉ | ○ | ○ | ○ |
| * Market surveillance (e.g. Regulation (EU) 2019/1020) | ○ | ○ | ◉ | ○ | ○ | ○ |
| * | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| Medicinal products (e.g. Regulation (EU) 726/2004, Directive 2001/83/EC) | ○ | ○ | ◉ | ○ | ○ | ○ |

* 6.94 Is there another field of coherence of the IVDR with other EU rules on which you would like to comment on?

- ◉ Yes
- ○ No

6.95 Please elaborate

MedTech Europe offers the following recommendations regarding legislations that require alignment with the IVDR:

• Environment sustainability legislation - MedTech Europe sees the need for a structured alignment of compliance deadlines of any environment regulation with IVDR specific regulatory system timelines. In particular, we recommend simplifying EU chemicals legislation, i.e. REACH Regulation (EU) 1907/2006, for any new restriction and authorisation of a substance used in a validated medical technology, the revised REACH Regulation should lay down a realistic and appropriate derogation period of at least 10 years for new products, which should also include their manufacturing processes, imports, and supply chain. New restrictions and authorisations should not apply on existing products already placed on the market. Options instead of restriction and derogation should also be considered where alternatives are not available and emissions/conditions are controlled. Additionally, the validity periods for RoHS Directive exemptions specific to medtech should also align with the IVDR timelines. The IVDR-specific guidance on "significant changes" should be reassessed to ensure it effectively supports innovation in sustainable materials.

• Circular Economy - MedTech Europe requests that the IVDR should not inhibit the circularity of medical technologies.

The specificities of medical technologies and its regulatory system should also be better taken into account in other EU legislation, for example including (not exhaustive list):

• Batteries Regulation
• EU Deforestation Regulation
• Product liability Directive & AI liability Directive (multiple cross-references about provisions related to product safety and duty of care that are not clarified. Impact with regards to presumption of liability).
• EHDS
• GDPR (the IVDR creates an overlap with the GDPR, particularly in areas like clinical investigations and post-market surveillance, where companies must comply with both regulations. However, the GDPR does not explicitly recognise IVDR compliance as a legal basis for processing personal data, creating legal uncertainty.)
• General Product Safety Regulation (some medical devices could fall under the provisions of GPSR with regards to online marketplaces and the applicability of this regulation in general for devices is unclear).
• Rules for EU health emergencies (IVDR derogations do not work)

Finally, with respect to question below (6.96) we stress that IVDR should continue to address device safety and performance. IVDR does not, and should not, cover sustainable production methods, which are already regulated under other specific EU legislation, including IED, REACH, RoHS, EU water and other local permitting legislation.

* 6.96 To what extent do you agree that existing rules facilitate the development of **sustainable production methods**?

- ○ Strongly disagree
- ◉ Disagree
- ○ Neutral
- ○ Agree
- ○ Strongly agree
- ○ Not applicable/ I don't know

6.97 To what extent do you agree that:

| | Strongly disagree | Disagree | Neutral | Agree | Strongly agree | Not applicable/ I don't know |
|---|---|---|---|---|---|---|
| * The provisions in the Regulation are coherent with one another | ○ | ◉ | ○ | ○ | ○ | ○ |
| * The provisions of the IVDR are coherent with the provisions of the MDR | ◉ | ○ | ○ | ○ | ○ | ○ |

* 6.98 Please explain by providing examples of where coherence within the Regulation is lacking.

Preambles 1 and 2 state objectives of the IVDR include supporting both innovation and SMEs, yet there are no specific requirements or measures in the articles of IVDR.

IVDR lacks coherence, particularly in its conformity assessment requirements under Article 48 and Annex IX, creating inconsistencies that impact regulatory clarity and efficiency.

Article 48 establishes conformity assessment routes but applies too-similar approaches in that it does not adequately differentiate between high-risk (Class D) and lower-risk (Class A, B, C) IVDs. This lack of proportionality creates unnecessary administrative burdens, particularly for low-risk devices.

Article 48 Conformity Assessment Procedures, requires devices which are sampled to follow section 4 of Annex IX. However in practice and according to MDCG 2019-13 (see section 5.2. Applicability of Chapter II, Section 4 of Annex IX) only Annex IX 4.1-4.18 are followed for such devices since no technical documentation assessment certificate is issued.

* 6.99 Please explain by providing examples of where coherence between the IVDR and MDR is lacking.

The concept of studies involving surgically invasive procedures was carried over from MDR to IVDR without fully considering the specificities of IVDs and despite there being no definition of ‘surgically invasive’ within

the IVDR text. As a result, IVDR performance studies that involve routine blood draws—where a small amount of blood is taken from participants and which pose minimal to negligible risk to the general population – are being treated similarly to studies where a surgical procedure is performed under anesthesia.

This mismatch in risk profiles has led to unnecessarily burdensome requirements for IVD performance studies without adding value for public health. Given the large number of studies that require routine phlebotomy, classifying them under Article 58.1 of IVDR poses unnecessary strains on the system and consumes significant resources for authorities, manufacturers and health institutions supporting research, diverting efforts from more critical regulatory needs.

## IVD - Efficiency of the EU rules on medical devices

When answering the following questions, please consider the following definitions.

**Compliance costs: the costs that need to be borne to comply with the provisions of the regulations.*

**Administrative costs: are part of compliance costs and are those costs borne by businesses, citizens, civil society organisations and public authorities as a result of administrative activities performed to comply with administrative obligations included in legal rules*

6.100 For the organisation you represent and based on your experience in the last 3 years, to what extent do you agree with the following:

**For phase 1**: activities related to generating evidence on the safety and performance of devices; activities related to performance studies; activities related to setting up quality management systems; activities for the designation of notified bodies under the Regulation

| | Strongly disagree | Disagree | Neutral | Agree | Strongly agree | Not applicable/ I don't know |
|---|---|---|---|---|---|---|
| * The costs for complying with the Regulation with regards to the activities listed are acceptable | ◉ | ○ | ○ | ○ | ○ | ○ |
| * Administrative costs for the activities listed are acceptable | ◉ | ○ | ○ | ○ | ○ | ○ |
| * The costs for complying with the Regulation with regards to the activities listed will decrease once the Regulation is fully implemented | ◉ | ○ | ○ | ○ | ○ | ○ |

| | | | | | | |
|---|---|---|---|---|---|---|
| * The administrative costs for the activities listed will decrease once the Regulation is fully implemented | ◉ | ○ | ○ | ○ | ○ | ○ |

6.101 For the organisation you represent and based on your experience in the last 3 years, to what extent do you agree with the following:

**For phase 2:** 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

| | Strongly disagree | Disagree | Neutral | Agree | Strongly agree | Not applicable/ I don't know |
|---|---|---|---|---|---|---|
| * The costs for complying with the Regulation with regards to the activities listed are acceptable | ◉ | ○ | ○ | ○ | ○ | ○ |
| * Administrative costs for the activities listed are acceptable | ◉ | ○ | ○ | ○ | ○ | ○ |
| * The costs for complying with the Regulation with regards to the activities listed will decrease once the Regulation is fully implemented | ◉ | ○ | ○ | ○ | ○ | ○ |
| * The administrative costs for the activities listed will decrease once the Regulation is fully implemented | ◉ | ○ | ○ | ○ | ○ | ○ |

6.102 For the organisation you represent and based on your experience in the last 3 years, to what extent do you agree with the following:

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

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | | Not applicable/ |

| | Strongly disagree | Disagree | Neutral | Agree | Strongly agree | I don't know |
|---|---|---|---|---|---|---|
| * The costs for complying with the Regulation with regards to the activities listed are acceptable | ◉ | ○ | ○ | ○ | ○ | ○ |
| * Administrative costs for the activities listed are acceptable | ◉ | ○ | ○ | ○ | ○ | ○ |
| * The costs for complying with the Regulation with regards to the activities listed will decrease once the Regulation is fully implemented | ◉ | ○ | ○ | ○ | ○ | ○ |
| * The administrative costs for the activities listed will decrease once the Regulation is fully implemented | ◉ | ○ | ○ | ○ | ○ | ○ |

6.103 For the organisation you represent and based on your experience in the last 3 years, to what extent do you agree with the following:

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

| | Strongly disagree | Disagree | Neutral | Agree | Strongly agree | Not applicable/ I don't know |
|---|---|---|---|---|---|---|
| * The costs for complying with the Regulation with regards to the activities listed are acceptable | ◉ | ○ | ○ | ○ | ○ | ○ |
| * Administrative costs for the activities listed are acceptable | ◉ | ○ | ○ | ○ | ○ | ○ |
| * The costs for complying with the Regulation with regards to the activities listed will decrease once the Regulation is fully implemented | ◉ | ○ | ○ | ○ | ○ | ○ |
| * | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| The administrative costs for the activities listed will decrease once the Regulation is fully implemented | ◉ | ○ | ○ | ○ | ○ | ○ |

* 6.104 To what extent do you agree that complying with one Regulation on medical devices at EU level decreases the **compliance costs** for your or the organisation you represent, compared to having to comply with different set of rules on *in vitro* diagnostic medical devices at national level ?

- ○ Strongly disagree
- ○ Disagree
- ○ Neutral
- ◉ Agree
- ○ Strongly agree
- ○ Not applicable/ I don't know

* 6.105 To what extent do you agree that complying with one Regulation on medical devices at EU level decreases the **administrative costs** for your or the organisation you represent, compared to having to comply with different set of rules on *in vitro* diagnostic medical devices at national level ?

- ○ Strongly disagree
- ○ Disagree
- ○ Neutral
- ◉ Agree
- ○ Strongly agree
- ○ Not applicable/ I don't know

* 6.106 To what extent do you agree that it is feasible to maintain adequately safe devices on the EU market while reducing costs?

- ○ Strongly disagree
- ○ Disagree
- ○ Neutral
- ◉ Agree
- ○ Strongly agree
- ○ Not applicable/ I don't know

## 8 Additional information

## 8.1 Do you have any additional comments you wish to share on the Regulations on medical devices?

1. Recertification

A robust PMS and a lifecycle approach to device safety and performance, is an integral part of MDR/IVDR and ensures continuing safety & performance of medical technologies. Concretely, Notified Bodies conduct a regular review of the manufacturers QMS and PMS requirements, PSUR and SS(C)P in addition to annual audits and assessing substantial changes for higher risk devices and certain product types. Today, on top of this, manufacturers must undergo a recertification process every 5 years. First experience shows that some Notified Bodies disregard previous history of the device as well as their own past review results and re-review the same documents (change notifications, PSURs, SSCPs…).SS(C)Ps, etc.). This is a costly, lengthy exercise which does not enhance safety and performance of devices.
Recertification poses a significant burden (incl. both FTE and financial) on manufacturers and may play a key role for some in making market decisions.

Other EU healthcare regulations such as Personal Protective Equipment do not require recertification. Other major jurisdictions do not require recertification (e.g. USA, Japan, Canada). MedTech Europe strongly suggests removing the recertification requirement. This will ensure continued availability of medical technologies in the EU, encourage competitiveness, streamline processes at manufacturer and NB level and help alleviate what MedTech Europe expects will become a certification bottleneck in 2027/2028.

2. Governance

Structural challenges are present in the governance system today e.g., in transparency, accountability, involvement of stakeholders. The existence of multiple actors: MDCG, Competent Authorities, designating authorities, European Commission, Notified Bodies, expert panels, JRC, EU reference laboratories, etc., there is a lack of clarity on who do manufacturers turn to for regulatory decisions.
There is no one ‘captain of the ship’ which can course-correct challenges and which has the responsibility and accountability for ensuring device availability. This leads to diverging practices and fragmentation which penalizes Europe’s competitiveness and hampers small businesses in particular.
To deliver on MDR/IVDR goals, the governance system needs to be urgently improved –industry’s concrete proposals for the roles and responsibilities of the future MedTech specific governance structure are attached.

3. Comments on specific questions:

To what extent do you agree that:
- the Regulation has contributed to protecting the health of patients in relation to medical devices?
- complying with one Regulation on medical devices at EU level decreases the compliance/ administrative costs (…), compared to having to comply with different set of rules on devices at national level?
- it is feasible to maintain adequately safe devices on the EU market while reducing costs?

While MedTech Europe agrees with these statements (and their equivalents for IVDs) on a conceptual level, we do not agree that the actual MDR/IVDR implementation and the way in which the system has been set up:

- has contributed to protecting patients health (even though MDR/IVDR included good concepts aimed at transparency, traceability (UDI)…). Device availability both current and innovative has been significantly affected.
- decreases compliance and administrative costs.
- allows to reduce costs and keep ‘all needed’ safe and performing legacy devices on the market.

Compared to the directives, cost of MDR/IVDR have increased exponentially (see MTE 2024 survey report), due to high administrative burden on industry (see full list of administrative burden). For instance, Summary of Safety and (Clinical) Performance (SS(C)P) must be made available in all the languages where a device

is envisaged to be sold. SS(C))P is a substantial document which needs to be updated, so must be the translations.
This is a costly and inefficient exercise for a document, which based on reports from manufacturers is rarely asked for, and if so, then only in its English version.
Therefore, SSCP should be made available by default in English only and can be made available translated on request without undue delay. This will decrease cost without impact on the device's safety and performance.

All MedTech Europe resources for IVDR/MDR targeted evaluation can be accessed via this link: https://www.medtecheurope.org/new-medical-technology-regulations/the-future-of-eu-medical-technology-regulatory-system/

If you wish to upload a document you can do so here. Please note that the uploaded document will be published alongside your response to the questionnaire.

### 8.2 Please upload your file(s)

Only files of the type pdf,txt,doc,docx,odt,rtf are allowed

## Contact

Contact Form