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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

Nick

* 2.9 Surname

sykes

* 2.10 Email (this won't be published)

nick.sykes.ext@efpia.eu

* 2.14 Organisation name

255 character(s) maximum

EFPIA

* 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.

38526121292-88

* 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
-
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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**	○	◉	○	○	○

* 5.4 What do you see as the most important barrier to the performance of CE-marked devices? 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
- [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

* 5.5 Please specify

Inefficient co-ordination of assessment of drug-device combination (DDC) products as well as a lack of communication between EMA and NBs re integral products; there is need for a communication pathway between NB, applicant and EMA. The roles and responsibilities between EMA and NB not always clear. The possibility to obtain scientific advice for the device constituent of a drug-device combination product is lacking

* 5.6 What do you see as the most important barrier to the safety of CE-marked devices? 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.)
- [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
- [ ] 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

*5.7 Please specify

The products are safe but the process for assessment and approval of drug-device combination (DDC) products is burdensome due to the split responsibility between EMA and NB – A key concern is the lack of clarity on the relevance of Economic Operator requirements, anything beyond Annex I being required when the drug and device are integral in the product, as well as labelling requirements of DDCs, given the lack of coordination between drug and device regulators

*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
- [ ] 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

*5.15 Please specify

There is a lack of communication between EMA and NBs regarding integral products. There is a need for a communication pathway between NB, applicant and EMA

Regarding Annex XVI products, there isn't sufficient MDCG guidance and more clarity and opportunity to comment is needed. There has been significant deviation between NBs in interpretation of Annex XVI requirements.

*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

Although the extension of the transition periods was needed to address acute CE mark expiry challenges and to allow more time for sponsors to ensure compliance with the new MDR requirements, there are many issues remaining. For example, clarity on responsibilities and duplication of effort in the oversight of drug-device combination (DDC) products. There remains long and unpredictable review timelines from the NBs, lack of harmonised interpretation of requirements, EUDAMED not fully functional.

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
- ☑ Other

* 5.47 Please specify

EUDAMED is incomplete so transparency is compromised.

* 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.

- ☑ 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
- [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

*5.51 Please specify

MDR has made the evaluation of drug-device combination (DDC) products much more complicated, with lack of clear roles and responsibilities, lack of alignment between timelines from EMA and NB, little clarity on labelling issues and unpredictability in connection with changes. In other countries DDCs are considered as one product and the authorities coordinate the assessment not the manufacturer. The current setup undermines regulatory stability, predictability and trust

Simplicity and clear responsibility in the application and approval process for DDC products is crucial to ensure quick access to innovative products in EU.

One way to achieve a more streamlined process with clear responsibility is to simplify the setup to a “one-door-entry” with one single authority being responsible for both the device part and the drug part of a DDC product including scientific advice, assessments and approval.

The process of acquiring a NB Opinion can be unpredictable, with varying timelines and no firm dates, which contrasts sharply with the EMA's defined timelines. The overall review time depends on reviewer availability at the NB, and the number of review rounds required, which cannot be predicted initially.

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
- [ ] 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

* 5.75 Please specify

In particular for developers of drug-device combination (DDC) products, there is a need to meet/manage expectations of both drug and device regulators adding an increased burden to such operators

* 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
- [ ] 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

* 5.77 Please specify

In particular for developers of drug-device combination (DDC) products, there is a need to meet/manage expectations of both drug and device regulators adding an increased burden to such operators

* 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
- [ ] 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

*5.79 Please specify

The main barriers to an equal playing field for all economic operators are: the regulatory complexities of the Regulation and inconsistencies of implementation in the different Member States; the smaller budget available to SMEs to comply with higher regulatory requirements, in particular multiple administrative requirements; and the limited transparency due to EUDAMED rollout delays.

*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
- [ ] 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
- [ ] Lack of support and incentives from the public sector
- [x] Lack of scientific and/or regulatory advice
- [x] Other

*5.89 Please specify

The setup for drug-device combination (DDC) products is complex, unpredictable and complicated to navigate within as the manufacturer has to comply with two sets of legislation; the medical device and legislation applicable to pharmaceuticals. This means that companies either choose or are forced to initially launch their products in non-EU markets than the EU, with the effect that patients in the EU are not able to receive innovative products as quickly as they should.

*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
- [ ] 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
- [ ] Lack of support and incentives from the public sector
- [x] Lack of scientific and/or regulatory advice
- [x] Other

*5.91 Please specify

The inability for experts from notified bodies to provide advice on development aspects to developers of devices, which leads to a lack of predictability during the development and bringing to market of innovative devices and drug-device combination (DDC) products.

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:

	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	○	○	◉	○	○	○

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

PPE Regulation 2016/425, the Product Liability Directive 85/374/EEC, GPSR Regulation 2023/988, CT Regulation 2014/536
But There is a great opportunity to streamline some of the requirements under the existing CTIS portal. We hope that the COMBINE pilot will demonstrate this.

* 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	○	◉	○	○	○	○

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

Delays in the full deployment of EUDAMED impact both IVDR and MDR but create inconsistencies in how manufacturers manage device registrations and surveillance data.

Risk Classification rules for a medical device software are different between IVDR and MDR. There should be, at a minimum, coherence in the risk classification approach for medical device software that provides information for diagnostic medical purpose whether it falls under IVDR or MDR.

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**	○	◉	○	○	○

* 6.4 What do you see as the most important barrier to the performance of CE-marked devices? 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
- [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

*6.5 Please specify

The main barriers are linked to stringent and sometimes inappropriate evidence requirements that are needed to demonstrate the performance of CE-marked devices - this is particularly true for legacy devices for which new clinical evidence is requested. These administrative requirements (many reports within the IVDR contain the same information that has to be provided in multiple reports) are leading to IVDs being taken off the market, or to decisions from overseas manufacturers or SMEs to not market innovation in the EU. In addition, the lengthier and complex approval process can delay the introduction of innovative devices. Furthermore, harmonisation across countries is impaired by additional national requirements to CE-marked products, diverging the interpretation of the IVDR, with demonstration of compliance which induces higher costs for testing. These increased administrative costs are without additional value for patients. Lastly, the misalignment between the IVDR and CTR is also a major barrier as well as the main factor delaying clinical trials patients' access to treatment.

*6.6 What do you see as the most important barrier to the safety of CE-marked devices? 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

*6.7 Please specify

The safety of CE-marked devices in the EU is affected by the delay of necessary tools like EUDAMED, as well as the delays or lack of harmonized standards. Technology is advancing faster than guidelines. Competent authorities might also lack resources to conduct post-market surveillance activities among Member States and NBs are overburdened due to the complexity of the Regulation causing the extension of transition deadlines and increase of cost of entry into the EU.

* 6.8 What do you see as the most important barrier to the robustness of quality checks before a device is placed on the market? 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
- [x] 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

* 6.9 Please specify

The main barrier to the robustness of quality check is the regulatory complexity and sometimes inappropriate IVDR requirements that lead to too burdensome compliance challenges. The lack of a proportionate and risk-based approach taking into account the historical compliance to IVDD is increasing costs in a disproportionate manner, without bringing additional benefits to patients. National Competent Authorities might also have additional requirements or diverging interpretation that are complicating the process. Unclear or inexistent guidelines on specific topics are also an issue, e.g. for AI-enabled IVDs. The lack of scientific guidance early in the development process is also an issue, particularly in case of co-development between a medicinal product and a companion diagnostic or an IVD. There is a need for a multi stakeholders platform (e.g. Scientific Advice) that includes IVD technical and technology experts (such as NBs).

* 6.10 What do you see as the most important barrier to meeting the specific needs of patients through the use of in-house and custom-made devices? 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

*6.11 Please specify

The in-house exemption which was designed to allow patients to benefit from testing in areas where there is no commercial test available is absolutely needed. However, it does not support all situations. In particular, the in-house exemption falls short in allowing innovative tests used in the context of investigational medicinal product trials. In this context, the tests may be provided by clinical research organisations, central laboratories or sponsors who may not be considered healthcare institutions and may not be based in the EU – therefore not able to use article 5.5 – and where the test will be used in a very controlled environment (approval, monitoring) for a limited period of time.

In addition, other key issues like the lack of harmonisation among Member States, the lack of standardisation and limited resources in Health institutions are limiting the benefit of the in-house exemption.

*6.12 What do you see as the most important barrier to identifying and addressing safety issues? 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

*6.13 Please specify

Stricter IVDR requirements leading to invest resources in meeting administrative requirements is diverting from investing resources in identifying and addressing safety signals at all levels. The lack of IT system and coordination at EU level have created inconsistencies in safety assessments and compliance. There is also lack of clarity on how AI can be used to detect safety signals and support analysis in the context of the IVDR.

*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 lack of technical and scientific expertise has led to disproportionate stringent requirements translating mostly in additional administrative burden. The lack of coordination at EU level (both in term of processes and IT support from EUDAMED), the lack of a centralised and harmonised interpretation of the requirements ahead of implementation, and the complexity of the requirements impeded the sector to be duly regulated. Additionally, the lack of multi-stakeholder scientific advice (including EMA, national Health Authorities and Notified Bodies) leads to divergent requirements in the development of IVDs together with medicinal products. The exclusion of NBs in scientific advice hinders a smooth development path.

*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 extended transition period has provided immediate relief to allow IVDs compliant with the IVD Directive to continue being available, however it does not solve the structural issues resulting from the Regulation, like the delay on innovation. In particular, the lack of coordinated assessment for Performance Study Application at EU level as well as diverging interpretation won't be solved by extending transition periods. The linkage between the EU CTR and EUDAMED will also not be solved. However, EFPIA strongly welcomes and supports the COMBINE project looking into cross sector and structural problems which is a step in the right direction.

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
- [ ] 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

* 6.47 Please specify

EUDAMED not being yet fully in place is a barrier to transparency of information on devices. Furthermore, the Summary of the Safety and Performance documents can only be uploaded to EUDAMED once devices are certified, and thus the certification process, availability of NBs and the documentation burden manufacturers before certification which becomes a bottleneck for transparency. Compliance to the GDPR can also limit sharing patient-specific data impacting transparency.

* 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
- [ ]

- [ ] 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

Barriers to traceability are EUDAMED which is not yet fully in place and this lack of harmonisation creates inconsistent levels of traceability across Europe. The compliance to the GDPR can also limit sharing patient-specific data and impact traceability.

*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
- [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

☑ Other

*6.51 Please specify

Trust could be enhanced by harmonising the interpretation and enforcement of the IVDR across Member States, removing complexity for economic operators, accelerating the implementation of EUDAMED, encouraging innovation with faster approval processes for innovative IVDs, including AI-based and personalised diagnostic tools while maintaining safety standards. Trust could also be improved by continuously updating guidelines to address emerging technologies, by installing scientific advice provided by all concerned stakeholders, including Health Authorities and Notified Bodies, also in early development of the devices.

Trust could also be improved by limiting the re-certification to a risk-based approach, as other jurisdictions outside of the European Union struggle understanding the limited validity of EU certificates.

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.

☑ 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
- [x] 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

Variability in how EU Member States and Notified Bodies interpret the same rules can lead to inconsistent application across stakeholders. The lack of a scientific, clinical and technical oversight to answer, in an EU harmonised manner (on IVDR, but also potentially on the interplay of other applicable legislations like the Medicinal Product legislation and the AI Act) to economic operators that have questions during the development process is an important barrier in the pre-market phase. The lack of a dispute resolution mechanism at EU level as well. The lack of guidance and scientific advice opportunities creates uncertainty on how rules are applied.

*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
- [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

*6.72 Please specify

Applying rules fairly and impartially to all stakeholders after a device is CE-marked can be affected by various elements, particularly in the post-market phase. These challenges can arise from gaps in regulatory enforcement, stakeholder dynamics, and systemic inefficiencies.

*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)
- [x] 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
- [x] 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

The main barriers to an equal playing field for all economic operators are: the regulatory complexities of the IVDR and inconsistencies of implementation in the different Member States; the smaller budget available to SMEs to comply with higher regulatory requirements, in particular multiple administrative requirements; and the limited transparency due to EUDAMED rollout delays.

* 6.75 What do you see as the most important barrier to the creation of an equal playing field for health institutions? 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

* 6.76 Please specify

The barriers to the creation of an equal playing field for health institutions are the lack of EU harmonised level playing field and an EU wide guidance on the quality management system and control of health institutions that may create divergent standards within EU. The lack of a consistent interpretation between Member States of the definition of a Health Institution is also an issue.

* 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.

- [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
- [ ] Lack of support and incentives from the public sector
- [x] Lack of scientific and/or regulatory advice
- [x] Other

* 6.84 Please specify

The barriers to competitiveness of the medical device sector are linked to the complexity of the IVDR which introduced multiple stricter administrative regulatory requirements. Some of these higher requirements are for the benefit of patients, however many others are just additional administrative requirements.

Member States' interpretation and implementation of the IVDR can differ which leads to inconsistencies

bringing uncertainty for economic operators and negatively impacting competitiveness.

Regulatory requirements for more complex and innovative devices are often unclear or not yet adapted to emerging technologies, delaying innovation in Europe. Compliance costs linked to administrative requirements and re-certification (even for IVDs being on the market for a long time) have also increased with IVDR and created a disproportionate impact for SMEs. In addition, the market fragmentation obliges manufacturers to navigate diverse requirements in different Member States related to pricing and reimbursement, creating additional complexity and reduced competition.

* 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
- [x] 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
- [x] Lack of scientific and/or regulatory advice
- [x] Other

* 6.86 Please specify

The main barriers to innovation in Europe are due to the regulatory complexity of the IVDR which impose stricter requirements for clinical evidence, safety and post-market surveillance. The lack of a risk-based approach is also an issue. While some of these requirements enhance safety for patients, they also increase time, costs and complexity to bring innovation to the market. Many of these requirements are mostly administrative, bringing very little benefits.

In addition, unclear pathways for emerging technologies discourages investments in cutting-edge technologies. Lastly, the variability of the interpretation and implementation of the IVDR by Member States creates inconsistency and does not encourage manufacturers to invest in Europe. The lack of multi-stakeholder scientific advice (with Notified Bodies) contributes to this shortcoming.

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

The IVDR needs to be coherent with the Clinical Trial Regulation (No. 536/2014) and with the revision of the pharmaceutical legislation and acknowledge that there is interplay between these legislations, especially when it comes to the development phase. Further alignment on the interplay of these regulatory frameworks is critical to ensure that both diagnostic tools and corresponding medicinal products can be developed, assessed, and marketed efficiently and safely. The misalignment of these legislations could also hinder the development of innovative therapies such as biomarker-based therapies. Further alignment is needed with the AI-ACT and Environment, Health and Safety. There is a great opportunity to streamline some of the IVDR requirements under the existing CTIS portal that the COMBINE pilot will hopefully demonstrate.

* 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.

There is incomplete guidance on the implementation of certain requirements, for example: clinical performance evaluation for innovative devices (e.g. AI driven diagnostics), use of IVDs not intended for clinical evaluation and CE marking in clinical trials or use of RWE to demonstrate clinical performance. This results in delays and uncertainties in conformity assessments.

There is also limited coordination between NBs and EMA or NCAs for medicinal products. This misalignment creates delays in the joint approval of diagnostics and medicinal products. Misalignment of NCAs on the interpretation of the legislation is also an issue (e.g. Art 58 and left over samples)

Coherence is also lacking in terms of documentation requirements for combined studies especially when Informed Consent Form is the same for the IVD and the pharmaceutical study.

Some of the requirements within IVDR have been directly imported from the MDR – which does not necessarily make sense. There may be a need to have slightly different definitions between MDR and IVDR, in particular when defining invasive sampling or medical purpose which, under the IVDR, may be more pertinent than relying on the MDR requirements.

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

Delays in the full deployment of EUDAMED impact both IVDR and MDR but create inconsistencies in how manufacturers manage device registrations and surveillance data.

A specific definition of intended purpose in the context of IVDR may benefit the whole sector rather than relying on a more general interpretation coming from the MDR.

Some of the requirements within IVDR have been directly imported from the MDR – which does not necessarily make sense. Only the requirements that are meaningful for IVDs should be included within IVDR. There may be a need to have slightly different definitions between both regulations, in particular when defining invasive sampling or medical purpose which, under the IVDR, may be more pertinent than relying on the MDR definitions.

Risk Classification rules for a Medical Device SoftWare are different between IVDR and MDR. Theres should be at a minimum coherence in the risk classification approach for MDSW that provides information for diagnostic medical purpose whether it falls under IVDR or MDR.

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

	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	○	◉	○	○	○	○

6.103 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?

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

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