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)
- ☐ Other company / business

* 2.4 Are you giving your contribution as a patient organisation?

Maximum 1 selection(s)

- ☐ Yes
- ☐ No

* 2.5 Are you giving your contribution as a health institution (Art 2(36) MDR/ Art 2(29) IVDR)?

Maximum 1 selection(s)

- ☐ Yes
- ☐ No

* 2.6 Are you giving your contribution as a healthcare professional/healthcare professional association?

Maximum 1 selection(s)

- ☐ Yes
- ☐ No

* 2.7 Please choose from the below

Maximum 1 selection(s)

- ☐ EU/EEA public authority
- ☐ non-EU/non-EEA public authority

* 2.8 First name

* 2.9 Surname

* 2.10 Email (this won't be published)

*2.11 Scope

- International
- Local
- National
- Regional

*2.12 Level of governance

- Local Authority
- Local Agency

*2.13 Level of governance

- Parliament
- Authority
- Agency

*2.14 Organisation name

255 character(s) maximum

*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.

*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
- Djibouti
- Dominica
- Libya
- Liechtenstein
- Saint Martin
-

- 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
- Bolivia
- 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
- Grenada
- 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
- Namibia
- 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
- Sweden

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

			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

* 2.18 **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

The type of respondent that you responded to this consultation as, your 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.

Public

Your name, the type of respondent that you responded to this consultation as, your country of origin and your contribution will be published.

* 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

3 Survey for citizens

If you are giving your contribution to this questionnaire as a healthcare professional, please select 'other' in question 2.2.

The following questionnaire relates to your views and experience with medical devices and in vitro diagnostic medical devices. For the purpose of answering the questions in this survey, please find below a short description of what medical devices and in vitro diagnostic medical devices are.

Medical devices: any apparatus, appliance, software, material or other article, including those that are implanted which is used for the diagnosis, prevention, monitoring, treatment or alleviation of diseases, injury or disability. Examples of medical devices include: sticking plasters, contact lenses, surgical masks, respiratory ventilators, pacemakers, breast implants, software apps and hip replacements.

In vitro diagnostic medical devices: devices that are used to perform tests on human samples (e.g. blood, urine, faeces) and provide important information on medical conditions that may assist healthcare

professionals and patients in delivering correct diagnosis, in monitoring the progression of an illness or impact of a prescribed treatment, and for screening. Examples of in vitro diagnostic medical devices include: HIV blood tests, COVID tests, pregnancy tests and blood sugar monitoring systems for diabetics.

3.1 In the last 3 years, have you or someone you know personally* used one of the medical devices in one or more of the following groups:

If you are answering based on your knowledge of the situation of someone you know personally, it should be for someone whose medical history you know.

	Yes	No
* Group 1 • Cardiac stent • Pacemaker • Breast implant • Hip implant • Cochlear implant • Intraocular lens • Other implantable devices	○	○
* Group 2 • HIV tests • Cancer tests • COVID tests • Remote monitoring devices for active implantable devices • Intra Uterine Devices (IUD) containing copper or silver • Dermal fillers • Test kits for measuring blood sugar • Self-testing devices for blood clotting	○	○
* Group 3 • Asthma inhalers • Pregnancy tests • Syringes • Glasses • Thermometers • A mobile app providing psychological exercises and hints for at-home use intended for treating depression • A mobile app intended to analyse a user's heartbeat, detect abnormalities and inform a physician accordingly	○	○
* Group 4 • I or someone I know personally used a device, but I don't know which of the other groups to select	○	○

The following questions concern the medical devices listed under **'group 1'** (e.g. cardiac stent, pacemaker, breast implant, hip implant, intraocular lens, other implantable devices)

* 3.2 To what extent do you agree that there was access to information on the device and how it would be used?

*In case you or someone you know personally have/has used multiple devices of this group, please respond to the question on the basis of the last device of this group that you/someo*ne you know personally have/has used

- Strongly disagree
- Disagree
- Neutral
- Agree
- Strongly agree
- I don't know

* 3.3 To what extent do you agree that sufficient information was provided on the risks associated with the device?

In case you or someone you know personally have/has used multiple devices of this group, please respond to the question on the basis of the last device of this group that you/someone you know personally have/has used

- Strongly disagree
- Disagree
- Neutral
- Agree
- Strongly agree
- I don't know

* 3.4 Please elaborate why it was not sufficient.

* 3.5 At the time of the use of the device, were you / was the person you know personally aware of 'implant cards'?

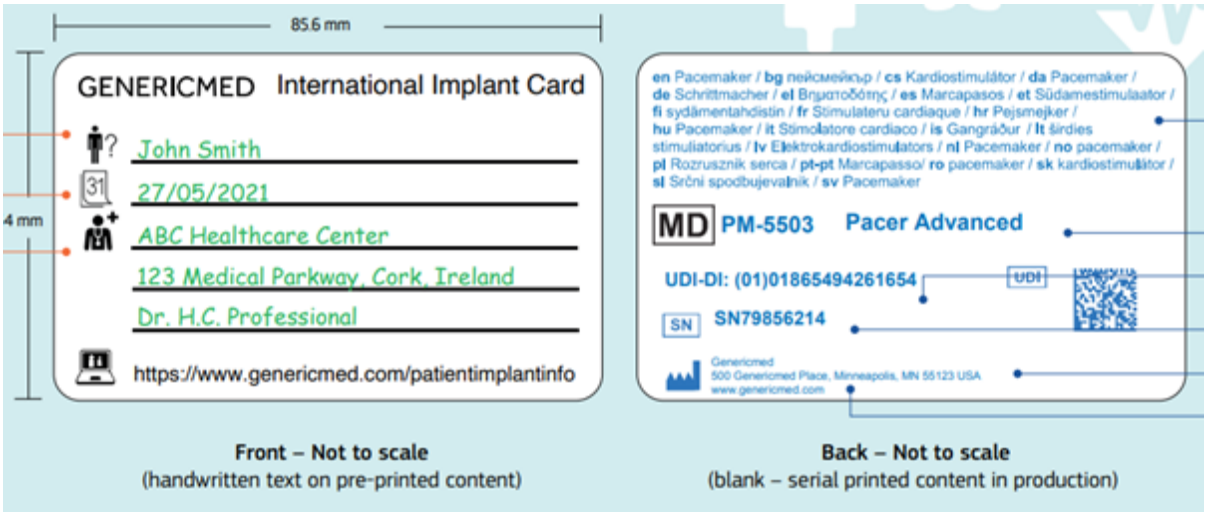
'Implant cards' are cards that are provided to patients that have an implanted medical device (see picture below). The card contains information allowing the identification of the device, including the device name, serial number, lot number, the unique device identifier, the device model, as well as the name, address and the website of the manufacturer.

Note that the following implantable medical devices do not require an implant card: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors. If you have experience with only these implantable medical devices, please tick the 'not applicable box'

- Yes
-

No

Not applicable



*3.6 At the moment of the use of the device, were you / was the user aware of the 'summary of safety and clinical performance' document?

The 'summary of safety and clinical performance' is a document that provides information on the clinical data available for the device and other information about the safety and clinical performance of the device.

Yes

No

*3.7 To what extent do you agree that you are / the person you know personally is aware of how to report an incident with the device?

In case you or someone you know personally have/has used multiple devices of this group, please respond to the question on the basis of the last device of this group that you/someone you know personally have/has used

Strongly disagree

Disagree

Neutral

Agree

Strongly agree

I don't know

The following questions concern the medical devices listed under **'group 2'** (e.g. HIV tests, Cancer tests, COVID tests, Remote monitoring devices for active implantable devices, Intra Uterine Devices (IUD, containing copper or silver, dermal fillers, Test kits for measuring blood sugar, Self-testing devices for blood clotting)

*3.8 To what extent do you agree that there was access to information on the device and how it would be used?

In case you or someone you know personally have/has used multiple devices of this group, please respond to the question on the basis of the last device of this group that you/someone you know personally have/has used

- Strongly disagree
- Disagree
- Neutral
- Agree
- Strongly agree
- I don't know

* 3.9 To what extent do you agree that sufficient information was provided on the risks associated with the device?

In case you or someone you know personally have/has used multiple devices of this group, please respond to the question on the basis of the last device of this group that you/someone you know personally have/has used

- Strongly disagree
- Disagree
- Neutral
- Agree
- Strongly agree
- I don't know

* 3.10 Please elaborate why it was not sufficient

* 3.11 At the moment of the use of the device, were you / was the user aware of the so-called ‘summary of safety and (clinical) performance’ document?

The ‘summary of safety and (clinical) performance’ is a document that provides information on the clinical data available for the device and other information about the safety and clinical performance of the device.

- Yes
- No

* 3.12 To what extent do you agree that you are / the person you know personally is aware of how to report an incident with the device?

In case you or someone you know personally have/has used multiple devices of this group, please respond to the question on the basis of the last device of this group that you/someone you know personally have/has used

- Strongly disagree
- Disagree
-

Neutral
- Agree
- Strongly agree
- I don't know

*3.13 In the last 3 years, was there an instance in which at least one specific device that you / the person you know personally wanted to use or should have used was not available?
- Yes
- No

*3.14 For the device that was not available, was an alternative device available?
- Yes
- No
- I don't know

*3.15 Was the performance of the alternative device as expected?
- Yes
- No
- Partially
- I don't know

*3.16 What was the impact of the device not being available? Please select all that apply
- The surgery was postponed
- The test could not be performed
- The treatment did not take place
- The waiting time for treatment was prolonged
- Had to go to another hospital to seek healthcare
- Had to go to another country to seek healthcare
- Other

The following questions concern the medical devices listed under **'group 3'** (e.g. Asthma inhalers, Pregnancy tests, Syringes, Glasses, Thermometers, A mobile app providing psychological exercises, etc) or any other device ('**group 4**').

*3.17 To what extent do you agree that there was access to information on the device and how it would be used?

- Strongly disagree
- Disagree
- Neutral
- Agree
- Strongly agree
- I don't know

*3.18 To what extent do you agree that sufficient information was provided on the risks associated with the device?

- Strongly disagree
- Disagree
- Neutral
- Agree
- Strongly agree
- I don't know

*3.19 Please elaborate why it was not sufficient

*3.20 To what extent do you agree that you are / the person you know personally is aware of how to report an incident with the device?

In case you or someone you know personally have/has used multiple devices of this group, please respond to the question on the basis of the last device of this group that you/someone you know personally have/has used.

- Strongly disagree
- Disagree
- Neutral
- Agree
- Strongly agree
- I don't know

*3.21 In the last 3 years, was there an instance in which at least one specific device that you / the person you know personally wanted to use or should have used was not available?

- Yes
- No

* 3.22 For the device that was not available, was an alternative device available?

- ○ Yes
- ○ No
- ○ I don't know

* 3.23 Was the performance of the alternative device as expected?

- ○ Yes
- ○ No
- ○ Partially
- ○ I don't know

* 3.24 What was the impact of the device not being available? Please select all that apply

- ☐ The surgery was postponed
- ☐ The test could not be performed
- ☐ The treatment did not take place
- ☐ The waiting time for treatment was prolonged
- ☐ Had to go to another hospital to seek healthcare
- ☐ Had to go to another country to seek healthcare
- ☐ Other

3.25 To what extent do you agree that medical devices and in vitro diagnostic medical devices are

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable/ I don't know
* regulated in a way that contributes to a high level of health protection?	○	○	○	○	○	○
* are safe to use?	○	○	○	○	○	○
* are sufficiently monitored in case of incidents?	○	○	○	○	○	○

* 3.26 To what extent do you agree that the medical device and in vitro diagnostics sector and its industry are duly regulated?

- ○ Strongly disagree
- ○ Disagree

- Neutral
- Agree
- Strongly agree
- I don't know

*3.27 What do you see as the most important issues?

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**					
* **Cross sector solutions** exist that allow for the EU-wide determination as to which					

legislation is applicable to a given product or type of product					
* A robust, transparent, predictable and sustainable **regulatory framework** exists					
* Requirements of **clinical evidence** are strengthened					
* The involvement of **external scientific and clinical expertise** has increased					
* The **oversight of notified bodies** is harmonised and meets stricter requirements					
* The **legal clarity and coordination in post market surveillance** is enhanced					
* **Cross sector solutions** exist that allow for the EU-wide determination as to which legislation is applicable to a given product or type of product					
* A robust, transparent, predictable and sustainable **regulatory framework** exists					
* Requirements of **clinical evidence** are strengthened					
* The involvement of **external scientific and clinical** expertise has increased					
* The **oversight of notified bodies** is harmonised and meets stricter requirements					
* The legal clarity and coordination in **post market surveillance** is enhanced					
* **Cross sector solutions** exist that allow for the EU-wide determination as to which legislation is applicable to a given product or type of product					
* A robust, transparent, predictable and sustainable **regulatory framework** exists					
* Requirements of **clinical evidence** are strengthened					
* The involvement of **external scientific and clinical expertise** has increased					
* The **oversight of notified bodies** is harmonised and meets stricter requirements					
* The legal clarity and coordination in **post market surveillance** is enhanced					

* 5.4 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
- [ ] 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

* 5.5 Please specify

* 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.)
- [ ] 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

*5.7 Please specify

*5.8 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.

- [ ] 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

*5.9 Please specify

*5.10 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.

- [ ] 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

*5.11 Please specify

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

*5.13 Please specify

*5.14 What do you think contributed to the sector not being duly regulated? 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

*5.15 Please specify

*5.16 To what extent do you agree that conformity assessment carried out in the EU are reliable in ensuring the quality and safety of devices?

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

* 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

* 5.19 How many certificates under the Regulation does your company hold?

If your organisation is not the manufacturer of a device, please indicate 'Not applicable/I don't know'.

* 5.20 Based on your portfolio, what is the average number of devices (by catalogue numbers – not individual units of catalogue number) covered by a certificate under the Regulation?

If your organisation is not the manufacturer of a device, please indicate 'Not applicable/I don't know'.

* 5.21 How many certificates under the Directive(s) does or did your company hold?

If your organisation is not the manufacturer of a device, please indicate 'Not applicable/I don't know'.

* 5.22 Based on your portfolio, what is/was the average number of devices (by catalogue numbers – not individual units of catalogue number) covered by a Directive certificate?

If your organisation is not the manufacturer of a device, please indicate 'Not applicable/I don't know'.

* 5.23 In the last 3 years, how many Manufacturer Incident Reports (MIRs) have you filed with a competent authority?

If your organisation is not the manufacturer of a device, please indicate 'Not applicable/I don't know'.

* 5.24 Has this number increased compared to the timeframe of 2014-2017?

If your organisation is not the manufacturer of a device, please indicate 'Not applicable/I don't know'.

- Yes
- No
- Not applicable/I don't know

* 5.25 Out of this number of MIRs filed in the last 3 years, what percentage have led to Field Safety Corrective Action and other safety related corrective actions?

If your organisation is not the manufacturer of a device, please indicate 'Not applicable/I don't know'.

* 5.26 Out of this number of MIRs filed in the last 3 years, after further analysis, how many have been demonstrated as not fulfilling the vigilance reporting requirements?

If your organisation is not the manufacturer of a device, please indicate 'Not applicable/I don't know'.

* 5.27 To what extent do you agree that the number of serious incidents that were severe* reported to your competent authority has decreased compared to 2017?

please consider those serious incidents that have led to death, to a serious public health threat or to serious health deterioration

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

* 5.28 In the last 3 years, have you or the members you represent experienced problems purchasing/being supplied with relevant devices?

- Yes
- No
- I don't know

* 5.29 Have you or the members you represent experienced cases where there was no alternative to the device that was not available?

- Yes
- No

* 5.30 What was the impact of the experienced shortages?

5.31 Based on you experience in the last 3 years, in case of a serious incident when using the device, to what extent do you agree that:

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable/ I don't know
* You were informed on where to report the issue?						
* You are reporting more safety issues now compared to 2017						

* 5.32 Based on your experience, what are the main reasons for the increase in reporting of safety issues? [select all that apply]

- [ ] Easier reporting of safety issues
- [ ] Higher number of safety issues
- [ ] Mandatory reporting
- [ ] Awareness raising through measures taken by a competent authority, such as an information campaign
- [ ] Other

* 5.33 Please elaborate

* 5.34 To what extent do you/the members you represent agree that there is more clinical data available on medical devices today compared to in 2017?

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

* 5.35 To what extent do you/the members you represent agree that the quality of the available clinical data on medical devices is better today compared to in 2017?

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

* 5.36 In the last 3 years, have the members you represent experienced problems purchasing/being supplied with relevant devices?

- ( ) Yes
- ( ) No
- ( ) I don't know

* 5.37 Have the members you represent experienced cases where there was no alternative to the device that was not available?
  - Yes
  - No

* 5.38 What was the impact of the experienced shortages?

* 5.39 Based on the experience of your members in the last 3 years, in case of a serious incident when using the device, to what extent does your organisation agree that information was available on where to report the issue?
  - Strongly disagree
  - Disagree
  - Neutral
  - Agree
  - Strongly agree
  - Not applicable/ I don't know

* 5.40 In the last 3 years, have you or the members you represent experienced problems purchasing/being supplied with relevant devices?
  - Yes
  - No
  - I don't know

* 5.41 Have you or the members you represent experienced cases where there was no alternative to the device that was not available?
  - Yes
  - No

* 5.42 What was the impact of the experienced shortages?

* 5.43 To what extent do/the members you represent agree that there is more clinical data available on medical devices today compared to in 2017?
  - Strongly disagree
  - Disagree
  - Neutral

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

*5.44 To what extent do you/the members you represent agree that the quality of the available clinical data on medical devices available is better today compared to in 2017?

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

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

* 5.48 What do you see as the most important barrier affecting the traceability of 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

*5.49 Please specify

*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
- [ ] 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

*5.51 Please specify

*5.52 Do you believe that some types of devices require an adapted identification solution to ensure proportionate traceability and registration?

- ( ) Yes
- ( ) No
- ( ) I don't know

*5.53 Please elaborate on the types of devices that would require an adapted identification solution and explain why

* 5.54 Do you believe that some types of devices require an adapted UDI labelling solution to ensure proportionate traceability?

- Yes
- No
- I don't know

* 5.55 Please elaborate on the types of devices that would require an adapted UDI labelling solution and explain why

* 5.56 Do you believe that some types of devices require an adapted identification solution to ensure proportionate traceability and registration?

- Yes
- No
- I don't know

* 5.57 Please elaborate on the types of devices that would require an adapted identification solution and explain why

* 5.58 Do you believe that some types of devices require an adapted UDI labelling solution to ensure proportionate traceability?

- Yes
- No
- I don't know

* 5.59 Please elaborate on the types of devices that would require an adapted UDI labelling solution and explain why

* 5.60 Do you believe that some types of devices require an adapted identification solution to ensure proportionate traceability and registration?

- Yes
- No
- I don't know

* 5.61 Please elaborate on the types of devices that would require an adapted identification solution and explain why

* 5.62 Do you believe that some types of devices require an adapted UDI labelling solution to ensure proportionate traceability?

- Yes
- No
- I don't know

* 5.63 Please elaborate on the types of devices that would require an adapted UDI labelling solution and explain why

* 5.64 To what extent do you agree that the current EU rules on medical devices help to enhance **trust in the safety and performance** of the devices your company manufactures/of your member companies/of the companies you represent /of the devices you import or distribute?

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

* 5.65 To what extent do you agree that the current EU rules on medical devices ensure that your devices/the devices of your member companies/companies you represent/ devices you import or distribute are **perceived as safe and trustworthy by healthcare professionals and patients**?

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

* 5.66 As part of your medical practice, have you handled **implantable medical devices**?

- Yes
- No

5.67 Are you aware of what so-called implant cards are and their use?

- Yes
- No

5.68 For those devices for which a **'summary of safety and clinical performance'** is available, have you or members of you team read it?

- Yes
- No

* 5.69 As part of your medical practice, have you handled **implantable medical devices**?

- Yes
- No

5.70 Are you aware of what so-called implant cards are and their use?

- Yes
- No

* 5.71 For implantable medical devices and based on the experience of your members in the last 3 years, to what extent do you agree that **patients are aware of what so-called ‘implant cards’ are**?

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

* 5.72 Based on the experience of your members in the last 3 years, to what extent do you agree that **patients are aware of what ‘summary of safety and clinical performance’ are**?

- Strongly disagree
-

Disagree

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

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.

- 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

* 5.75 Please specify

* 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.

- [ ] 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

* 5.77 Please specify

* 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.

- [ ] 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

* 5.79 Please specify

* 5.80 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.

- [ ] 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

* 5.81 Please specify

* 5.82 Based on your experience/the experience of your members, to what extent do you agree that the conformity assessment actvities carried out by notified bodies designated under the MDR/IVDR (i.e. after 2017) are harmonised?

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

* 5.83 Please explain in which way the activities are not harmonised

* 5.84 *The following question covers the time period before the new EU rules on medical devices entered into force in 2017.*
Based on your experience/the experience of your members, to what extent do you agree that conformity assessment activities carried out by notified bodies designated under the previous Directives MDD/AIMDD/IVDD (i.e. between 2013 - 2017) were harmonised?

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

* 5.85 Please explain in which way the activities were not harmonised

* 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.

- ☐ 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

*5.89 Please specify

*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.

- [ ] 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

*5.91 Please specify

*5.92 Which kind of technical documents does your organisation use the most in designing and manufacturing devices?

If your organisation is not the manufacturer of a device, please indicate 'Not applicable/I don't know'.

- Harmonised European Standards
- International Standards
- Common Specifications
- Other technical specifications
- Not applicable/I don't know

* 5.93 Based on your portfolio, in how many other jurisdictions (outside of EU + EEA) were you able to place devices on the market because they hold the EU CE marking?

- 0-10
- 11-25
- 26-50
- 51-75
- 76-100
- 101-125
- 126-150
- More than 150

* 5.94 In the last 3 years, how many certificates of free sales has your authority issued?

* 5.95 Does this represent an increase of free sales certificates issued compared to the period of 2014-2017?

- Yes
- No
- I don't know

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

* 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.

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

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**					
*					

Cross sector solutions exist that allow for the EU-wide determination as to which legislation is applicable to a given product or type of product					
* A robust, transparent, predictable and sustainable **regulatory framework** exists					
* Requirements of **clinical evidence** are strengthened					
* The involvement of **external scientific and clinical expertise** has increased					
* The **oversight of notified bodies** is harmonised and meets stricter requirements					
* The **legal clarity and coordination in post market surveillance** is enhanced					
* **Cross sector solutions** exist that allow for the EU-wide determination as to which legislation is applicable to a given product or type of product					
* A robust, transparent, predictable and sustainable **regulatory framework** exists					
* Requirements of **clinical evidence** are strengthened					
* The involvement of **external scientific and clinical** expertise has increased					
* The **oversight of notified bodies** is harmonised and meets stricter requirements					
* The legal clarity and coordination in **post market surveillance** is enhanced					
* **Cross sector solutions** exist that allow for the EU-wide determination as to which legislation is applicable to a given product or type of product					
* A robust, transparent, predictable and sustainable **regulatory framework** exists					
* Requirements of **clinical evidence** are strengthened					
* The involvement of **external scientific and clinical expertise** has increased					
* The **oversight of notified bodies** is harmonised and meets stricter requirements					
*					

The legal clarity and coordination in **post market surveillance** is enhanced	○	○	○	○	○

*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
- ☐ 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

*6.5 Please specify

*6.6 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.)
- ☐ 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

*6.7 Please specify

*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.

- [ ] 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

*6.9 Please specify

*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.

- [ ] 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

*6.11 Please specify

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

*6.13 Please specify

*6.14 What do you think contributed to the sector not being duly regulated? 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

*6.15 Please specify

*6.16 To what extent do you agree that conformity assessment carried out in the EU are reliable in ensuring the quality and safety of devices?

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

* 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

* 6.19 How many certificates under the Regulation does your company hold?

If your organisation is not the manufacturer of a device, please indicate 'Not applicable/I don't know'.

* 6.20 Based on your portfolio, what is the average number of devices (by catalogue numbers – not individual units of catalogue number) covered by a certificate under the Regulation?

If your organisation is not the manufacturer of a device, please indicate 'Not applicable/I don't know'.

* 6.21 How many certificates under the Directive(s) does or did your company hold?

If your organisation is not the manufacturer of a device, please indicate 'Not applicable/I don't know'.

* 6.22 Based on your portfolio, what is/was the average number of devices (by catalogue numbers – not individual units of catalogue number) covered by a

Directive certificate?

If your organisation is not the manufacturer of a device, please indicate 'Not applicable/I don't know'.

* 6.23 In the last 3 years, how many Manufacturer Incident Reports (MIRs) have you filed with a competent authority?

If your organisation is not the manufacturer of a device, please indicate 'Not applicable/I don't know'.

* 6.24 Has this number increased compared to the timeframe of 2014-2017?

If your organisation is not the manufacturer of a device, please indicate 'Not applicable/I don't know'.

- Yes
- No
- Not applicable/I don't know

* 6.25 Out of this number of MIRs filed in the last 3 years, what percentage have led to Field Safety Corrective Action and other safety related corrective actions?

If your organisation is not the manufacturer of a device, please indicate 'Not applicable/I don't know'.

* 6.26 Out of this number of MIRs filed in the last 3 years, after further analysis, how many have been demonstrated as not fulfilling the vigilance reporting requirements?

If your organisation is not the manufacturer of a device, please indicate 'Not applicable/I don't know'.

* 6.27 To what extent do you agree that the number of serious incidents that were severe* reported to your competent authority has decreased compared to 2017?

*please consider those serious incidents that have led to death, to a serious public health threat or to serious health deterioration

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

* 6.28 In the last 3 years, have you or the members you represent experienced problems purchasing/being supplied with relevant devices?

- ○ Yes
- ○ No
- ○ I don't know

* 6.29 Have you or the members you represent experienced cases where there was no alternative to the device that was not available?

- ○ Yes
- ○ No

* 6.30 What was the impact of the experienced shortages?

* 6.31 In the last 3 years, have you or the members you represent experienced problems purchasing/being supplied with relevant devices?

- ○ Yes
- ○ No
- ○ I don't know

* 6.32 Have you or the members you represent experienced cases where there was no alternative to the device that was not available?

- ○ Yes
- ○ No

* 6.33 What was the impact of the experienced shortages?

* 6.34 In the last 3 years, have you or the members you represent experienced problems purchasing/being supplied with relevant devices?

- Yes
- No
- I don't know

* 6.35 Have you or the members you represent experienced cases where there was no alternative to the device that was not available?

- Yes
- No

* 6.36 What was the impact of the experienced shortages?

6.37 Based on you experience in the last 3 years, in case of a serious incident when using the device, to what extent do you agree that:

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable/ I don't know
* You were informed on where to report the issue?						
* You are reporting more safety issues now compared to 2017						

* 6.38 Based on your experience, what are the main reasons for the increase in reporting of safety issues? [select all that apply]

- Easier reporting of safety issues
- Higher number of safety issues
- Mandatory reporting
- Awareness raising through measures taken by a competent authority, such as an information campaign
- Other

* 6.39 Please elaborate

* 6.40 To what extent do/the members you represent agree that there is more clinical data available on *in vitro* diagnostic medical devices today compared to in 2017?
  - Strongly disagree
  - Disagree
  - Neutral
  - Agree
  - Strongly agree
  - Not applicable/ I don't know

* 6.41 To what extent do you/the members you represent agree that the quality of the available clinical data on *in vitro* diagnostic medical devices available is better today compared to in 2017?
  - Strongly disagree
  - Disagree
  - Neutral
  - Agree
  - Strongly agree
  - Not applicable/ I don't know

* 6.42 To what extent do you/the members you represent agree that there is more clinical data available on *in vitro* diagnostic medical devices today compared to in 2017?
  - Strongly disagree
  - Disagree
  - Neutral
  - Agree
  - Strongly agree
  - Not applicable/ I don't know

* 6.43 To what extent do you/the members you represent agree that the quality of the available clinical data on *in vitro* diagnostic medical devices available is better today compared to in 2017?
  - Strongly disagree
  - Disagree
  - Neutral

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

*6.44 Based on the experience of your members in the last 3 years, in case of a serious incident when using the device, to what extent does your organisation agree that information was available on where to report the issue?

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

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.

- [ ] 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

* 6.47 Please specify

* 6.48 What do you see as the most important barrier affecting the traceability of 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

*6.49 Please specify

*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.

- [ ] 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

*6.51 Please specify

*6.52 Do you believe that some types of devices require an adapted identification solution to ensure proportionate traceability and registration?

- ( ) Yes
- ( ) No
- ( ) I don't know

*6.53 Please elaborate on the types of devices that would require an adapted identification solution and explain why

*6.54 Do you believe that some types of devices require an adapted UDI labelling solution to ensure proportionate traceability?

- Yes
- No
- I don't know

*6.55 Please elaborate on the types of devices that would require an adapted UDI labelling solution and explain why

*6.56 Do you believe that some types of devices require an adapted identification solution to ensure proportionate traceability and registration?

- Yes
- No
- I don't know

*6.57 Please elaborate on the types of devices that would require an adapted identification solution and explain why

*6.58 Do you believe that some types of devices require an adapted UDI labelling solution to ensure proportionate traceability?

- Yes
- No
- I don't know

*6.59 Please elaborate on the types of devices that would require an adapted UDI labelling solution and explain why

*6.60 Do you believe that some types of devices require an adapted identification solution to ensure proportionate traceability and registration?

- Yes
- No
- I don't know

* 6.61 Please elaborate on the types of devices that would require an adapted identification solution and explain why

* 6.62 Do you believe that some types of devices require an adapted UDI labelling solution to ensure proportionate traceability?

- Yes
- No
- I don't know

* 6.63 Please elaborate on the types of devices that would require an adapted UDI labelling solution and explain why

* 6.64 To what extent do you agree that the current EU rules on medical devices help to enhance **trust in the safety and performance** of the devices your company manufactures/of your member companies/of the companies you represent /of the devices you import or distribute?

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

* 6.65 To what extent do you agree that the current EU rules on medical devices ensure that your devices/the devices of your member companies/companies you represent/ devices you import or distribute are **perceived as safe and trustworthy by healthcare professionals and patients**?

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

6.66 For those devices for which a **'summary of safety and performance'** is available, have you or members of you team read it?

- Yes
- No

* 6.67 Based on the experience of your members in the last 3 years, to what extent do you agree that **patients are aware of what 'summary of safety and performance' are**?

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

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
- [ ] 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

* 6.70 Please specify

* 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.

- [ ] 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

*6.72 Please specify

*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.

- [ ] 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

*6.74 Please specify

*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.

- [ ]

- [ ] 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

* 6.76 Please specify

* 6.77 Based on your experience/the experience of your members, to what extent do you agree that the conformity assessment activities carried out by notified bodies designated under the IVDR (i.e. after 2017) are harmonised?

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

* 6.78 Please explain in which way the activities are not harmonised

* 6.79 *The following question covers the time period before the new EU rules on medical devices entered into force in 2017.*

Based on your experience/the experience of your members, to what extent do you agree that conformity assessment activities carried out by notified bodies designated under the IVDD (i.e. between 2013 - 2017) were harmonised?

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

* 6.80 Please explain in which way the activities were not harmonised

* 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

* 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.

- [ ] 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

* 6.86 Please specify

* 6.87 Which kind of technical documents does your organisation use the most in designing and manufacturing devices?

If your organisation is not the manufacturer of a device, please indicate 'Not applicable/I don't know'.

- ( ) Harmonised European Standards
- ( ) International Standards
- ( ) Common Specifications
- ( ) Other technical specifications
- ( ) Not applicable/I don't know

* 6.88 Based on your portfolio, in how many other jurisdictions (outside of EU + EEA) were you able to place devices on the market because they hold the EU CE marking?

- ( ) 0-10
- ( ) 11-25
- ( ) 26-50
- ( ) 51-75
- ( ) 76-100
- ( ) 101-125
- ( ) 126-150
- ( ) More than 150

* 6.89 In the last 3 years, how many certificates of free sales for IVDs has your authority issued?

* 6.90 Does this represent an increase of free sales certificates issued for IVDs compared to the period of 2014-2017?

- Yes
- No
- I don't know

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

* 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.

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

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

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

*7.1 To what extent do you agree that enough materials and explanations are being provided to understand the EU Regulations on medical devices adopted in 2017?

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

7.2 Have you encountered challenges in your reliance framework on the EU rules on medical devices?

- [ ] Yes
- [ ] No

*7.3 What are the challenges you have encountered in your reliance framework on the EU rules on medical devices?

* 7.4 Are there any provisions in the MDR/IVDR that you consider not addressing your needs and you have therefore not integrated in your respective regulatory frameworks?

- ○ Yes
- ○ No

* 7.5 Please elaborate on which provisions these are and why you consider them not addressing your needs?

* 7.6 What types of tools would you consider important for your regulatory framework to consider a/continue its reliance programme on the European Union?

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