# FACTUAL SUMMARY REPORT ON THE PUBLIC CONSULTATION FOR THE TARGETED EVALUATION OF THE EU RULES ON MEDICAL DEVICES AND IN VITRO DIAGNOSTICS

*This document should be regarded solely as a summary of the contributions made by stakeholders in the public consultation launched in the context of the targeted evaluation of the MDR and IVDR. It cannot in any circumstances be regarded as the official position of the Commission or its services. Responses to the consultation activities cannot be considered as a representative sample of the views of the EU population.*

## 1.1 Introduction

Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR) aim to ensure a better protection of public health and patient safety, whilst supporting innovation. The objective of the public consultation is to gather feedback on the effectiveness, efficiency, relevance, coherence and EU added value of both Regulations from 2017 to 2024.

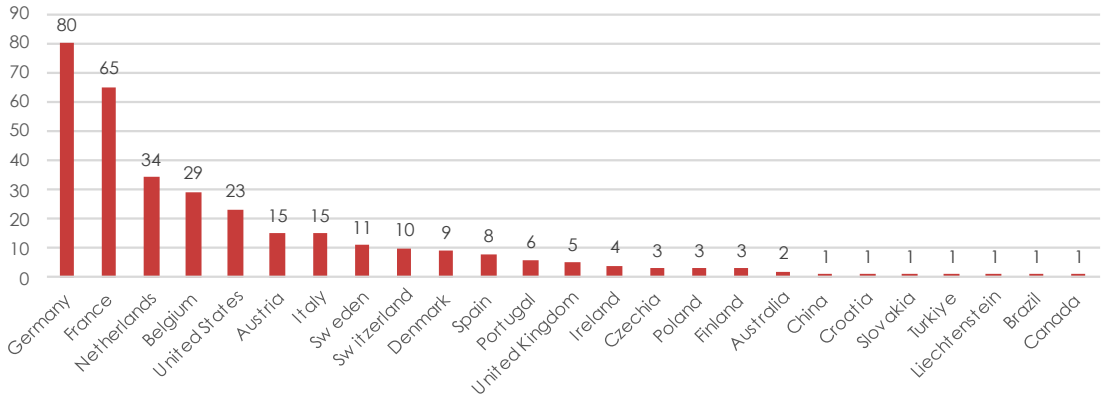
The public consultation was available from 12 December 2024 to 21 March 2025 in 24 official languages of the EU via the European Commission's Have your say webpage. The overall number of responses was 332. No duplicates or campaigns were identified, and feedback rules were respected. 51 attachments uploaded in the public consultation have been published[1].

This factual summary report provides an overview of the number of responses, characteristics of respondents, and some of their views and concerns. A full analysis of the public consultation, together with all other consultation activities, will be included in the synopsis report that will be published with the evaluation report.

## 1.2 Who contributed and whom are they representing?

Responses were obtained from 16 EU Member States, which accounted for 86% of the total responses (332 responses). The majority of replies (42% or 145) were submitted by individuals in Germany and France (see Figure 1). In contrast, 14% of responses were from respondents in non-EU countries.[2] Most of the respondents completed the survey in English (45%,151 out of 332).

*Figure 1 Response by country*

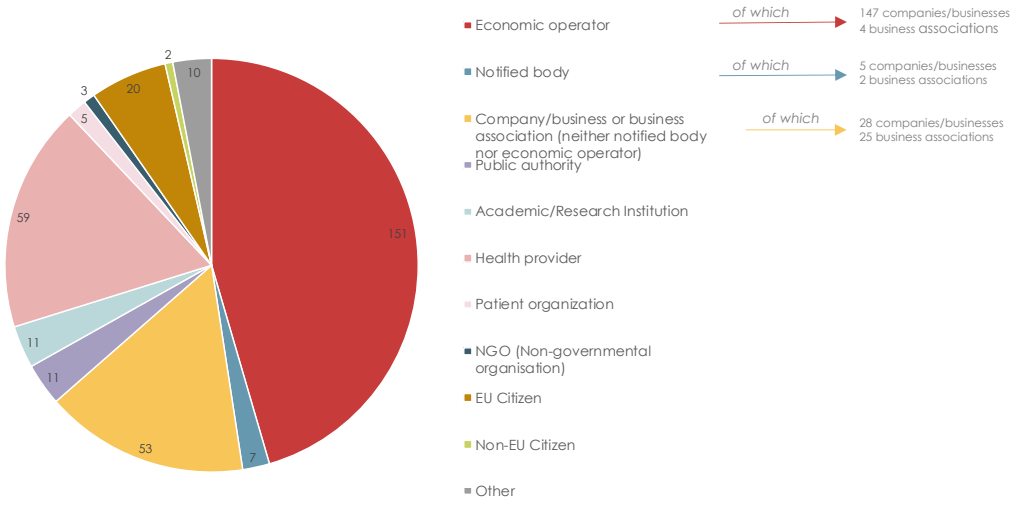



[1] 52 respondents uploaded attachments in the public consultation. In line with the feedback rules, 1 document has not been published and will be discarded in subsequent analyses.

[2] United States (23); Switzerland (10); United Kingdom (5); Australia (2); China (1); Turkiye (1); Liechtenstein (1); Brazil (1); Canada (1).

Respondents selected their stakeholder group via a user type[3] question, followed sub-questions asking for further detail (e.g., companies/businesses identified as notified bodies, economic operators, or other). They could also indicate affiliation with specific categories of interest, namely: patient organisations or health providers[4]. Each respondent was assigned to a single stakeholder category. If affiliated with a specific category of interest, they were excluded from others[5]. For example, a company identified as both an economic operator and a health provider was classified as a "health provider." Thus, only those notified bodies and economic operators not also identifying as patient organisations or health providers are included in those categories, see Figure 2.

*Figure 2. Survey respondents by stakeholder type*




As shown in Figure 2, a large number of responses (151/332 or 45%) came from economic operators , of which 59 were large-sized companies (250+ employees), 43 were medium (50-250 employees), 32 were small (10-50 employees) and 17 were micro (less than 10 employees). Also of note, of the responses from public authorities[6] (n = 11), the majority were national authorities (n = 8), 2 were regional and 1 was a local authority.

## 1.3 What aspects are addressed?

The survey was structured into three distinct chapters:

1. Questions for citizens (medical devices and *in vitro* diagnostic medical devices)
2. Questions for all stakeholder types except citizens (medical devices)
3. Questions for all stakeholder types except citizens (*in vitro* diagnostic devices)

The chapters of the survey presented to respondents were based on their answers to two questions: i) their stakeholder type and ii) the selection of chapters on medical devices and *in vitro* diagnostic medical devices.

[3] Possible responses: academic/research institution, business association, company/business, consumer organisation, EU citizen, environmental organisation, non-EU citizen, NGO, public authority, trade union, other.

[4] Health providers was a composite category made up of those who indicated they were either a health institution, a healthcare professional/healthcare professional association, or both.

[5] One respondent that was categorised as "health provider" was not categorised also as "patient organisation".

[6] Public authorities were agencies and authorities, no respondents indicated they represented parliament.

A small number of respondents answered to questions in both chapters on medical devices and *in vitro* diagnostic medical devices (n = 48).

## 1.4 What are their views and concerns?

### *1.4.1 Citizens (all device types)*

Twenty EU citizens and two non-EU citizens responded to the survey. Experience with medical devices and *in vitro* diagnostic medical devices among these respondents was high, with around 75% of respondents stating that they or someone they knew personally had used devices from the 3 major groups of devices in the last three years[7]. Only one respondent (out of 16 responses in total) stated that in the last three years, there was an instance in which at least one specific device that they / the person they knew personally wanted to use or should have used was not available. In general, the majority of citizens (12/16) agreed that there was access to information on the device and its usage.

Further, citizens tended to agree that medical devices and *in vitro* diagnostic medical devices are sufficiently monitored (62% or 13/21 agreed[8]), safe to use (62% or 13/21 agreed) and regulated in a way that contributes to a high level of health protection (67% or 14/21).

### *1.4.2 Medical devices (all stakeholder types except citizens)*

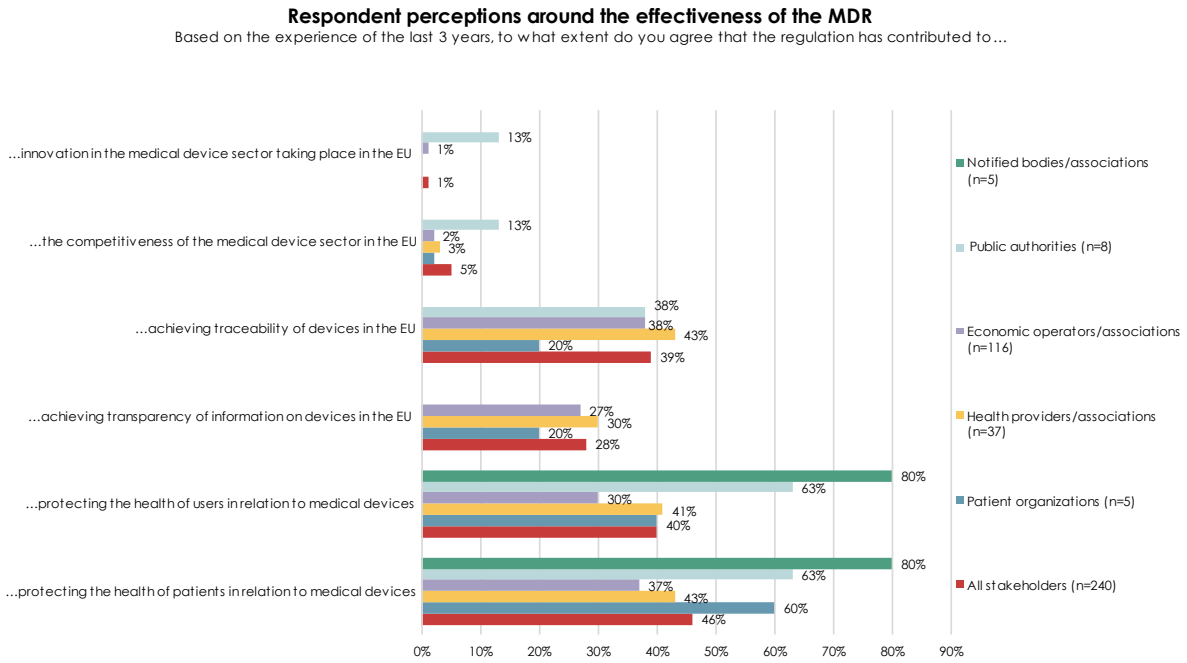
240 respondents answered the questions about medical devices and the MDR. Regarding the **effectiveness**, just under half of respondents agreed that the Regulation had contributed to protecting the health of patients and users, a smaller proportion agreed that it had contributed to achieving transparency and traceability of devices in the EU, and very few agreed that the Regulation had contributed to the competitiveness of and innovation in the medical devices sector in the EU (see Figure 33, red bars).

Perceptions were then examined across different sector-specific stakeholder groups that were of interest: notified bodies, economic operators, public authorities, health providers and patient organisations. While there are some differences in percentages across sector-specific stakeholder groups, no explicitly disagreeing views were observed. Indeed, comparisons are difficult due to varying response numbers per stakeholder; while notified bodies, public authorities, and patient organisations appear to view the MDR's effectiveness in protecting the health of patients and users more positively, their low response rates limit data reliability (see the number of responses per group in the legend of Figure 33).

[7] 15/21 respondents reported use (personal or otherwise) of Group 1 devices (Cardiac stent, Pacemaker, Breast implant, Hip implant Cochlear implant, Intraocular lens, Other implantable devices, 16/21 respondents reported use (personal or otherwise) of Group 2 devices 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)7, and 15/21 respondents reported use (personal or otherwise) of Group 3 devices 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.).

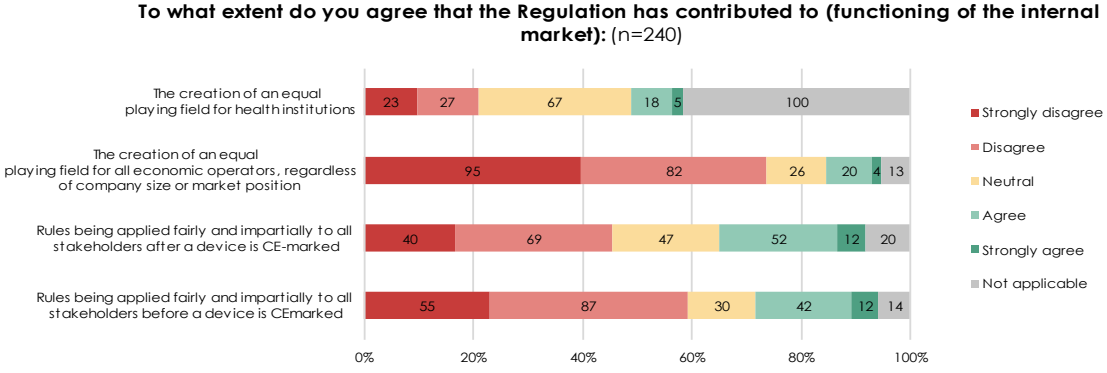
[8] Agreed = a response of « agree » or « strongly agree ». This logic is followed in the presentation of the results in this report for all subsequent questions of this type.

*Figure 33. Respondent perceptions around the effectiveness of the MDR*




Concerning the contribution of the Regulation to the functioning of the internal market, respondents were more likely to agree that the Regulation had contributed to the rules being applied fairly and impartially to all stakeholders (both before and after a device is CE-marked), and much less likely to agree that it had contributed to the creation of a level playing field (see Figure 4. 4).

*Figure 4. 4 Respondent perceptions of the contribution of the MDR to the functioning of the internal market*




Regarding the **efficiency** of the Regulation, around half of the respondents agreed that complying with one Regulation on medical devices at EU level decreased the compliance costs (49% or 117/240) and administrative costs (50% or 119/240) to them or the organisation they represent, compared to having to comply with different set of rules on medical devices at national level. Further, 45% (109/240) agreed that it was feasible to maintain adequately safe devices whilst reducing costs. Perceptions of the costs associated

with the MDR were fairly negative; for Phase 1[9] and Phase 2[10] activities, less than 10% of respondents (15 /240 and 10/240) agreed that the costs for complying with the Regulation were acceptable, that the administrative costs for the activities were acceptable, and that both of these would decrease once the Regulation was implemented. Perceptions on the acceptability of administrative and compliance costs were slightly more positive in this regard for Phase 3[11] (agreement ranging from 7% to 13%) and Phase 4[12] activities (agreement ranging from 10% to 15%).

Regarding the **internal coherence** of the Regulation, 35% of respondents (84/240) agreed that the provisions in the Regulation are coherent with one another, and 33% (78/240) agreed that the provisions of the MDR are coherent with the provisions of the IVDR. Regarding **external coherence**, perceptions varied according to the Regulation with which it was being compared. Respondents were most likely to agree that the Regulation was coherent with other EU rules in the field of market surveillance (33% or 78/240) and packaging and labelling (34% or 81/240), and least likely to agree it was coherent with other regulations in the field of eco-design (4% or 10/240).

Regarding the **relevance** of the MDR, respondents were most likely to agree that the Regulation addressed cybersecurity (30% or 71/240) and least likely to agree that it addressed environmental sustainability (11% or 26/240). Regarding the **EU added value** of the Regulation, 93% of respondents (or 224/240) agreed that it was preferable to have one EU regulation in this field instead of individual national regulations.

#### *1.4.3 In vitro diagnostic medical devices (all stakeholder types except citizens)*

113 respondents responded to questions about *in vitro* diagnostic medical devices and the IVDR. Regarding the **effectiveness**, less than half of respondents agreed that the Regulation had contributed to protecting the health of patients and users in relation to medical devices, a smaller proportion agreed that it had contributed to achieving transparency and traceability of devices in the EU, and very few agreed that the Regulation had contributed to the competitiveness of and innovation in the medical devices sector in the EU (see Figure 5), similar to results for the MDR.

As for the MDR, perceptions were then examined across different sector-specific stakeholder groups that were of interest. Health providers tended to have a more negative perspective regarding the Regulation's contribution to the protection of patients and users. Note that no responses were submitted from patient organizations in the IVDR section. Notified bodies were more likely than other stakeholder types to agree that the IVDR was effective in protecting the health of patients and users, whereas health providers were less likely to agree. Other than this, response patterns were fairly similar across stakeholder groups of interest.

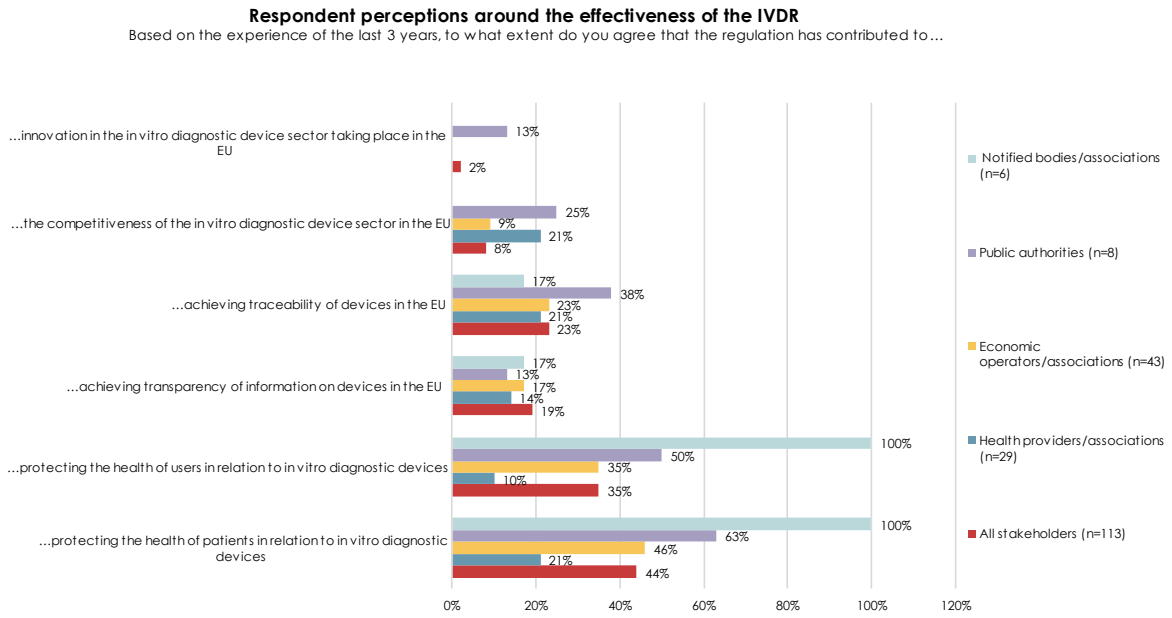
[9] Activities related to generating evidence on the safety and performance of devices; activities related to clinical investigations; activities related to setting up quality management systems; activities for the designation of notified bodies under the Regulation/

[10] 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.

[11] Activities for the compliance with post market obligations; activities related to vigilance; activities related to market surveillance.

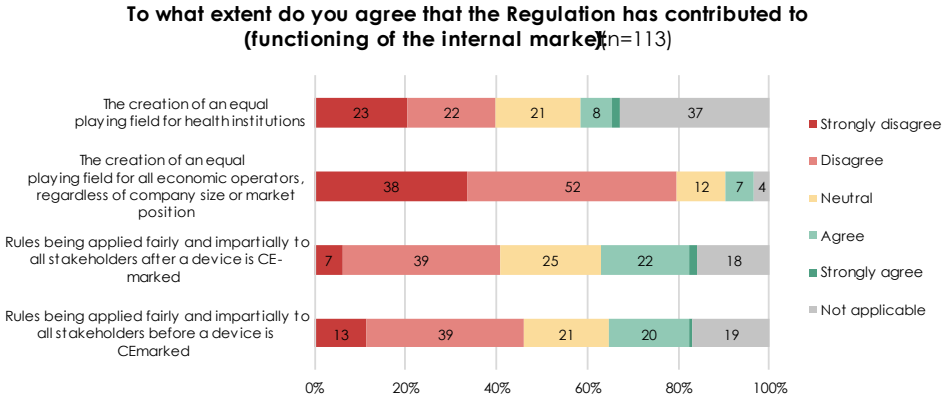
[12] Activities for providing information on devices or certificates; activities providing guidance to the sector.

*Figure 5 Respondent perceptions around the effectiveness of the IVDR*




Concerning the contribution of the Regulation to the functioning of the internal market, respondents were more likely to agree that the Regulation had contributed to the rules being applied fairly and impartially to all stakeholders (both before and after a device is CE-marked), and much less likely to agree that it had contributed to the creation of a level playing field, see Figure 6.

*Figure 6 Stakeholder perceptions of the contribution of the IVDR to the functioning of the internal market*




Regarding the **efficiency** of the Regulation, around a third of the respondents agreed that complying with one Regulation on *in vitro* diagnostic devices at EU level decreased the compliance costs (32% or 36/113) to them or the organisation they represented, compared to having to comply with different set of rules on medical devices at national level. As such, perceptions on this point were less positive for the IVDR than for the MDR (where half of respondents agreed). Over half agreed that the IVDR decreased administrative costs (56% or 63/113) and 42% of respondents (or 48/113) agreed that it is feasible to maintain adequately safe devices on the EU market while reducing costs. Just 10% or less of respondents agreed that the costs for complying with the Regulation were acceptable and that the administrative costs for the activities were acceptable, across

Phases 1 to 4; for Phase 1 and 4, 13 to 18% agreed that costs would decrease once the Regulation was implemented.

Regarding the **internal coherence** of the Regulation, 35% of respondents (39/113) agreed that the provisions in the Regulation are coherent with one another, and 44% (50/113) agreed that the provisions of the IVDR are coherent with the provisions of the MDR which is more than when respondents were asked the same question on the MDR (33%). Regarding **external coherence**, perceptions varied according to the Regulation with which the IVDR was being compared. Respondents were most likely to agree that the Regulation was coherent with other EU rules in the field of cybersecurity (34% or 39/113) and market surveillance (31% or 35/113), and least likely to agree it was coherent with other regulations in the field of eco-design (4% or 4/113).

Regarding the **relevance** of the IVDR, respondents were most likely to agree that the Regulation addressed cybersecurity (35% or 40/113) and least likely to agree that it addressed environmental sustainability (13% or 15/113). These findings are consistent with responses to the MDR portion of the consultation. Companies/businesses agreed more strongly that the Regulation was relevant than other stakeholder groups.

Regarding the **EU added value** of the Regulation, 87% of respondents (or 98/113) agreed that it was preferable to have one EU regulation in this field instead of individual national regulations covering these same aspects. Agreement was significantly higher among companies/businesses and business associations than it was among academic/research institutions.