Study supporting the monitoring of the availability of medical devices on the EU market

3rd survey for MD and IVD manufacturers and authorised representatives

HaDEA/2021/P3/03

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Austrian National Public Health Institute / Gesundheit Österreich GmbH (GÖG),
Stubenring 6, 1010 Vienna, Austria, phone no.: +43 1 515 61,
websites: https://goeg.at, https://ppri.goeg.at, https://medizinprodukteregister.at

Gesundheit Österreich GmbH

Areté The Agri-food Intelligence Company

CIVIC CONSULTING

European Commission

1 Background and introduction

Background

The European Commission's Directorate-General for Health and Food Safety (DG SANTE) – via its European Health and Digital Executive Agency (HaDEA) – commissioned a "**Study supporting the monitoring of the availability of medical devices on the EU market**" from a consortium led by the Austrian National Public Health Institute (Gesundheit Österreich GmbH / GÖG) in collaboration with Areté and Civic Consulting.

The **general objective** of the study, which started in December 2022 and will last 42 months, is **to support the monitoring of the availability of medical devices on the EU market** in the context of the implementation of regulations[1] on medical devices and *in vitro* diagnostic medical devices **from the perspectives of key stakeholders**. Large stakeholder consultations are conducted in the context of this study.

To be able to monitor the availability of medical devices (incl. *in vitro* diagnostics) on the European market, it is **vital to obtain information from manufacturers (MF) of medical device and *in vitro* diagnostics as well as from authorised representatives (AR).** We kindly ask all manufacturers and authorised representatives, including those who plan to place MDR and IVDR compliant devices on the market in the next two years, to respond to the survey.

Note: This is already the third survey round with manufacturers and authorised representatives in this study. The first survey round took place from November 2023 to January 2024, the second between December 2024 to March 2025. The question set in this survey is very similar to the questions in the previous surveys to allow for comparability of the results to some extent. The study team is aware that between the survey rounds the deadlines for transitioning medical devices from the relevant directives to the new regulations came into effect, which had an impact on the rephrasing of some of the questions. The questions were developed in collaboration with the MDCG Task Force (TF) on certification capacity monitoring and industry representatives.

The results of the first two survey rounds with economic operators (EOs) have been compiled and analysed by the study team and are published: Link to the dashboard, Presentation incl. results of the 1st EO survey, Presentation incl. results of the 2nd EO survey

We will keep any company-specific information (raw data) collected strictly confidential and under no circumstances will we disclose individualised company-level information. The **aggregated, company-neutral data** will be analysed in the form of synopsis reports (presentations) and published in a **dashboard**.

To participate in the online survey: https://ec.europa.eu/eusurvey/runner/3rd_EO_survey

We hope to reach as many economic operators as possible and intend to keep the workload for completing the survey to a minimum.

Kindly provide **only ONE answer per company and question**. Please check internally with your colleagues to make sure that only one answer per company is provided.

You can download the current version of the survey questionnaire from the menu on your right.

Instructions on how to answer to the survey:

- Navigate through the questionnaire using the next buttons at the end of each page.
- To change replies, it is sufficient to go back to the question and modify it.
- A draft of the survey in progress can be saved via the dedicated button on the right end of each page. If you wish to pause the survey, please be sure to save your progress by clicking on the button "Save as draft" before closing your session: this will generate a personalised link with your survey draft. Re-loading the page after a time out will not recover previous answers. We recommend saving the progress and click on the new link provided by EUSurvey once you are ready to finish the survey.
- In some questions, additional instructions can be provided in italics (e.g.: select all that apply) – additional instructions will appear in case of errors in the answer (e.g.: "This is not a valid e-mail address.").
- Fields marked with (*) are mandatory. In case of missing mandatory replies, an error message ("This field is required.") in red is displayed on the relevant section of the question when the respondent moves forward in the questionnaire.

[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 (Medical devices regulation – MDR), Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 (In vitro diagnostic medical devices regulation – IVDR)

- To submit your replies please be sure to proceed until the very last page by clicking the "submit" button at the bottom of said page.
- After submitting the questionnaire, this message will be displayed: "We thank you for your time spent taking this survey. Your response has been recorded". A summary of the replies is provided and can be downloaded in PDF or printed.

You can find a glossary of the terms used in this survey at the following link: here

Markings: Questions marked with 18. NB survey are also asked in the 18th notified body survey.

Survey deadline: 28 February 2026

Data protection, data processing and consent to participate

Acting in full compliance with EU competition law, and within its limits, we will keep any company-specific information (raw data) collected strictly confidential and under no circumstances will we disclose individualised company-level information. Only aggregated survey outcomes will be published in the data dashboard and analysis reports.

The project leader, the Austrian National Public Health Institute (Gesundheit Österreich GmbH / GÖG), is responsible for overall project management as well as the concept and analysis of the survey, Areté is providing support with consultation activities (implementation in EUSurvey tool, distributing surveys, data collection and pseudonymisation) while the third project partner (Civic Consulting) has no access to data.

This survey is run via the online tool EUSurvey. The raw data entered in the survey are stored on the servers of the European Commission's Data Centre pursuant to the Commission Decision (EU, Euratom) 2017/46 of 10 January 2017 on the security of communication and information systems in the European Commission. More information is available at: https://ec.europa.eu/eusurvey/home/privacystatement

Once the survey has closed, the raw data will be downloaded by a member of the project team bound by a duty obligation of confidentiality. In a second step, pseudonymisation will take place: identification and contact information (as provided in Questions 1a, 1b and 1c) will be deleted from the data file and replaced by an anonymous id code. A separate decoding document will be generated; only selected members of the project team will have access to the document for validation purposes. The decoding document will be handled with the utmost confidentiality and will not be shared, under any circumstances, with non-authorised personnel or with entities outside the study team.

The elaboration of survey replies will be based on the pseudonymised data file only.

The decoding document will be used to perform preliminary data validation activities (e.g., to check for double submissions). In the case of suspected double submissions, the project team will contact the company concerned for consultation. In the case of confirmed double submissions, the data entry concerned will be deleted after informing the company about the deletion.

During the elaboration of survey replies, ongoing validation of the pseudonymised data will take place to detect potential inconsistencies within the replies. Only in the case of severe concerns about a data entry will the survey reply concerned be decoded by an authorised member of the project team after consulting the company concerned.

For processing and subsequent publication, the data will be entered in aggregated form in the dashboard tool (using MS PowerBI). Before publication in the dashboard, the aggregated survey results are subject to review by DG SANTE and the MDCG TF on NB capacity monitoring. It is guaranteed that it will not be possible to trace back individual companies in the aggregated data.

With the submission of your data/information you agree to these terms. We follow the EC privacy statement: https://ec.europa.eu/info/law/better-regulation/specific-privacy-statement_en.

Contact

If you have any queries, please contact the study team via medical.devices@goeg.at.

Acronyms used:

AIMDD = Active Implantable Medical Device Directive

AR = Authorised Representative

CER = Clinical Evaluation Report

DB = Distributor

EMDN = European Medical Device Nomenclature

EO = Economic Operator

EU = European Union

IFU = Instructions for Use

IM = Importer

IVD = *In Vitro* Diagnostic Medical Device

IVDD = IVD Directive (EC) 98/79/EG

IVDR = IVD Regulation (EU) 2017/746

OEM = Original Equipment Manufacturer

OBL = Own Brand Labelling / Labelled

MD = Medical device

MDD = Medical Device Directive 93/42/EEC

MDR = MD Regulation (EU) 2017/745

MF = Manufacturer

PSUR = Periodic Safety Update Reports

SME = Small and Medium-Sized Enterprises[2]

SSCP = Summary of Safety and Clinical Performance

QMS = Quality Management System

[2] *Definition:* The category of micro, small and medium-sized enterprises (SMEs) is made up of enterprises which employ fewer than 250 persons and which have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million. (Source: Extract from Article 2 of the Annex to Recommendation 2003/361/EC)

2 Questionnaire

The questions marked with a **red asterisk** * are **mandatory** and must be completed to progress with the survey.

2.1 About you and your company

ABOUT

1. **Please provide your contact details**. *

   We value your privacy. This information will be used to identify / delete any double submissions by the same company/subsidiaries. We may contact you in case we have any questions about your submission or to send you survey results. We will not share your personal details – they will be deleted as soon as they are no longer needed to process the results. Full anonymity is guaranteed.

   a. **Name** of the **company**: *[free text]*
   b. **Name of the person** completing the **survey**: *[first name and surname]*
   c. **Contact details:**
      - e-mail address: *[free text]*
      - phone no.: *[free text]*

2. **Please indicate the country** where your company is based?[3]* *[List of EU-27 Member States and "non-EU"]*

   In case of "non-EU":
   - Please state the country where your company is based: *[free text]*
   - In which country is/are your authorised representative(s) based? *[List of EU-27 Member States plus Turkey, Norway, Iceland and Liechtenstein and option "I have no authorised representative yet."]*

3. Are you already **registered in EUDAMED**? * *[multiple choice question]*
   a. Yes, I am registered as a **manufacturer**.
      - [optional] If yes, please provide the **Single Registration Number (SRN)** or **Actor ID** of the **manufacturer** in EUDAMED (e.g., AT-MF-000000001): *[free text; limited to 15 characters in total (including dashes) if available]*
   b. Yes, I am registered as an **authorised representative**.
      - [optional] If yes, please provide the **Single Registration Number (SRN)** or **Actor ID** of the **authorised representative** in EUDAMED (e.g., AT-AR-000000001): *[free text; limited to 15 characters in total (including dashes) if available]*
   c. Yes, I am registered as an **importer**.
      - [optional] If yes, please provide the **Single Registration Number (SRN)** or **Actor ID** of the **importer** in EUDAMED (e.g., AT-IM-000000001): *[free text; limited to 15 characters in total (including dashes) if available]*
   d. No, but the contracted authorised representative is registered.
      - [optional] Please provide the **Single Registration Number (SRN)** or **Actor ID** of your **authorised representative(s)** in EUDAMED (e.g., AT-AR-000000001): *[free text; limited to 15 characters in total (including dashes) if available]*
   e. No

4. What is the **size of the legal entity of your organisation** (globally)? * *[single choice]*

   Source of the definition: Extract of Article 2 of the annex to Recommendation 2003/361/EC

[3] This is the country where the company for which you are completing the survey is based. In the case of a multinational company this might be the country where the headquarters is located if you are replying on behalf of the entire company. In case you are replying on behalf of a subsidiary, please indicate the country where the subsidiary is based and make sure that your answers only refer to the subsidiary.

- micro (an enterprise which employs fewer than 10 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 2 million)
- small (an enterprise which employs between 10 and 50 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 10 million)
- medium (an enterprise which employs between 51 and 250 persons, and which have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million)
- large (an enterprise larger than a medium enterprise)

5. Is your company a **start-up**? * (Start-ups are companies or ventures that are focused on new and innovative products or services that the founders want to bring to market)
   - Yes
   - No
6. Did you already answer to previous survey rounds in the context of this study? *
   - Yes
   - No
   - I don't know.
7. Please indicate where your **products (CE-marked under AIMDD/MDD/MDR or IVDD/IVDR) are currently made available**: * *[multiple choice question]*
   - Inside the European Union (EU)
   - Outside the European Union
     - Select continents *[list of continents]*
       - Africa
       - Asia
       - Australia
       - Europe (outside the EU)
       - North America
       - South America
   - Products are not available yet.

Purpose of this question: to get an indication whether products are marketed worldwide or only within the EU.

8. Which **device areas** (EMDN categories) are currently included in your **product portfolio** on the **EU market** to date [31/10/2025]? Please select the relevant EMDN categories. (optional response)
   [multiple choice to select relevant EMDN categories]

Notes:

- The **European Medical Device Nomenclature (EMDN)** aims at supporting the functioning of the European database on medical devices (EUDAMED). It will be utilised by manufacturers for the registration of medical devices in EUDAMED and primarily serves regulatory purposes to support MDR and IVDR requirements. (Source: https://webgate.ec.europa.eu/dyna2/emdn/)
- Please tick the relevant categories.
- *Purpose of this question*: to learn which devices are placed on the market by your company as a manufacturer or for which you are the authorised representative; to learn in which market segment the company is operating.

- A – DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION
- B – HAEMATOLOGY AND HAEMOTRANSFUSION DEVICES
- C – CARDIOCIRCULATORY SYSTEM DEVICES
- D – DISINFECTANTS, ANTISEPTICS, STERILISING AGENTS AND DETERGENTS FOR MEDICAL DEVICES
- F – DIALYSIS DEVICES
- G – GASTROINTESTINAL DEVICES
- H – SUTURE DEVICES
- J – ACTIVE-IMPLANTABLE DEVICES
- K– ENDOTHERAPY AND ELECTROSURGICAL DEVICES
- L – REUSABLE SURGICAL INSTRUMENTS
- M – DEVICES FOR GENERAL AND SPECIALIST DRESSINGS
- N – NERVOUS AND MEDULLARY SYSTEMS DEVICES
- P – IMPLANTABLE PROSTHETIC AND OSTEOSYNTHESIS DEVICES
- Q – DENTAL, OPHTHALMOLOGIC AND ENT DEVICES
- R – RESPIRATORY AND ANAESTHESIA DEVICES

- S – STERILISATION DEVICES (EXCLUDING CAT. D – Z)
- T – PATIENT PROTECTIVE EQUIPMENT AND INCONTINENCE AIDS (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT – PPE)
- U – DEVICES FOR UROGENITAL SYSTEM
- V – VARIOUS MEDICAL DEVICES
- W – *IN VITRO* DIAGNOSTIC MEDICAL DEVICES
    - W01 – REAGENTS
        - CLINICAL CHEMISTRY
        - IMMUNOCHEMISTRY (IMMUNOLOGY)
        - HAEMATOLOGY / HAEMOSTASIS / IMMUNOHAEMATOLOGY / HISTOLOGY / CYTOLOGY
        - MICROBIOLOGY (CULTURE)
        - INFECTIOUS DISEASES
        - GENETIC TESTING
    - W02 – IVD INSTRUMENTS
        - CHEMISTRY / IMMUNOCHEMISTRY INSTRUMENTS
        - HEMATOLOGY / HISTOLOGY / CYTOLOGY INSTRUMENTS
        - MICROBIOLOGY INSTRUMENTS (CULTURES)
        - INFECTIOUS IMMUNOLOGY INSTRUMENTS
        - NUCLEIC ACID TESTING INSTRUMENTS
        - SAMPLE PROCESSING SYSTEMS
        - GENERAL PURPOSE IVD INSTRUMENTS
        - IVD INSTRUMENTS – OTHER
    - W03 – IVD GENERIC USE CONSUMABLES
        - SAMPLES COLLECTION DEVICES
        - DEVICES FOR SAMPLES TRANSPORT (non-generic laboratory products)
        - DEVICES FOR SAMPLES ANALYSES (no laboratory generic products)
        - IVD GENERAL USE CONSUMABLE-DEVICES – OTHER ACCESSORIES
        - IVD GENERAL USE CONSUMABLE DEVICES – OTHER
- Y– DEVICES FOR PERSONS WITH DISABILITIES NOT INCLUDED IN OTHER CATEGORIES
- Z – MEDICAL EQUIPMENT AND RELATED ACCESSORIES, SOFTWARE AND CONSUMABLES

9. In which **role(s)** does your company operate*: *[multiple choice question; companies operating in different roles and fields will be asked to complete several surveys]*
    - Manufacturer (MF)
        - For medical devices *(trigger for survey **MF–MD** (manufacturer of MD)*
        - For in vitro diagnostics *(trigger for survey **MF–IVD** (manufacturer of IVD)*
    - Authorised representative (AR) *(trigger for survey **AR**)*

2.2 MD: Questionnaire on medical devices

MD

The questions marked with a **red asterisk** * are **mandatory** and must be completed.

AIMDD/MDD – legacy devices[4]*

Purpose of these questions: to get to know how many AIMDD/MDD devices (legacy devices) and certificates remaining valid according to Article 120(2) MDR your company has (still) to date and how many of the devices will be transitioned to MDR. It should give an indication of the expected availability of the company's medical devices on the market after transitioning to the MDR.

**This refers to the catalogue number (not individual units of the catalogue number).

10. **Total number of AIMDD/MDD devices**** (in terms of the number of devices referring to the catalogue number) placed on the market **to date** [31/10/2025]: *[free text – number of devices referring to catalogue numbers]*
    - Of this total number, please specify the **number of MDD devices** that will be **up-classified under the MDR** and will need NB intervention for the first time AND that you plan to transition to the MDR and is not MDR certified yet: *[free text – number of devices referring to catalogue numbers]*

11. **Total number of EC certificates issued** in accordance with Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) prior to 26 May 2021 **benefitting of the extended transitional period** provided for in Article 120 MDR to date [31/10/2025]: *[free text – no. of certificates (QMS + product certificates)]*

Notified bodies – written agreements, refused applications

Purpose of these questions: to understand how many companies have written agreements with notified bodies. Written agreements can be framework agreements with NBs (covering several applications) or contracts for each application (signed by the NB and manufacturer). This indication should help clarify how far companies are in the transition process (application – written agreement – certificates) to the MDR and whether they could use the time also in the light of the extension to the MDR transitional period (Regulation (EU) 2023/607).

Written agreements

12. Do you have **written agreements** with (a) notified body(ies) designated under the MDR?* *[select one option]*

    18. NB survey

- Not applicable – my devices do not need notified body involvement.
- Yes, all of the devices are covered by written agreements with one or several notified body(ies).
- Yes, but only some of the devices are covered by a written agreement with one or several notified body(ies).
- No written agreement signed.

  Please specify why: *[free text]*

12.1 **If yes**: Which devices are covered in this/these written agreement(s)?* *[single-choice]*

- Only legacy devices.
- Legacy and "new" devices (devices which have never been CE-marked but will need CE-marking under the MDR to access the EU market).
- Only new devices.

[4] In line with MDCG 2021-252 'legacy devices' should be understood as devices, which, in accordance with the MDR's transitional provisions, are placed on the market after the MDR's date of application (i.e. 26 May 2021) if certain conditions are fulfilled.

Refused applications

13. Did a notified body **refuse an application[5] under the MDR**? *

- Yes
    - (optional) If yes, please indicate the average time passed since application was sent until refusal *[drop down]*
        - Less than 6 months
        - 6–12 months
        - 13–18 months
        - 19–24 months
        - more than 24 months
    - If yes, what were the reasons for the refusal?
        - Application deemed incomplete: *[no. of refused applications]*
            - Please specify reasoning of NB: *[free text, optional]*
        - Wrong qualification of product/classification of device: *[no. of refused applications]*
        - Wrong conformity assessment procedure: *[no. of refused applications]*
        - Outside the scope of the notified body's designation: *[no. of refused applications]*
        - Insufficient notified body resources: *[no. of refused applications]*
        - Other: [no. of refused applications] *[free text specifying the "other" reason for refusal]*
    - If yes *[multiple choice]*:
        - For legacy devices
        - For "new" devices (devices which have never been CE-marked but will need CE-marking under the MDR to access the EU)
- No, my company has not sent an application yet.
- No, applications were not refused so far.
- Not applicable – my devices do not need notified body involvement.

MDR implementation – applications, certificates, time periods

Purpose of these questions: to monitor the progress of the transition status of devices to the MDR and to get an indication of the future workload for notified bodies.

Applications

14. How many **applications**** in total have you **lodged** under the MDR to your notified body(ies) [up to 31/10/2025]?* If there are no applications for an Annex, please write "0". 18. NB survey

Note:

**This number also includes applications with issued certificates, ongoing applications and applications that were ultimately refused. Please note that applications lodged for changes to existing MDR certificates are included as well but should also be indicated separately. Pre-application activities are not included. We ask you to complete all rows.

- Annex IX(I&III): *[free text – no. of applications; of which no. of applications lodged for changes]*
- Annex IX(II): *[free text – no. of applications; of which no. of applications lodged for changes]*
    - Of which no. of applications requiring consultation procedure for devices incorporating medicinal substance: *[free text – no. of applications]*
    - Of which no. of applications requiring consultation for tissues or cells of human origin or their derivates: *[free text – no. of applications]*
    - Of which no. of applications requiring consultation procedure for devices based on substances or combination of substances: *[free text – no. of applications]*
- Annex X: *[free text – no. of applications, of which no. of applications lodged for changes]*
- Annex XI(A): *[free text – no. of applications; of which no. of applications lodged for changes]*
- Annex XI(B): *[free text – no. of applications; of which no. of applications lodged for changes]*

[5] Application = submission for certification

- *All Annexes:* Of which no. of applications covering new devices (devices which have never been CE-marked but will need CE-marking under the MDR to access the EU market): *[free text – no. of applications]*

15. How many **devices** (catalogue number**) are **undergoing the MDR conformity assessment process** (accepted MDR applications still under review by NB) to date [31/10/2025]? Please provide a total number as well as a breakdown per MDR risk class.*

- Total: *[free text – number of devices referring to catalogue numbers]*
- Class Ir: *[free text – number of devices referring to catalogue numbers]*
- Class Is: *[free text – number of devices referring to catalogue numbers]*
- Class Im: *[free text – number of devices referring to catalogue numbers]*
- Class IIa: *[free text – number of devices referring to catalogue numbers]*
- Class IIb: *[free text – number of devices referring to catalogue numbers]*
- Class III: *[free text – number of devices referring to catalogue numbers]*

Note: **This refers to the catalogue numbers (not individual units of the catalogue number).

Certificates

16. **Have you already received certificates under the MDR to date** [up to 31/10/2025]? *
    - Yes *(trigger for Q17-Q18, Q27- Q28)*
        - 16.1 If yes, did you already have a certificate renewed under the MDR?
            - Yes *(trigger for Q24-Q26)*
            - No
    - No

If yes to Q16:

17. How many **certificates** have already been issued under the MDR by Annex for your portfolio **to date** [up to 31/10/2025]? If no certificates have been issued, please enter "0".* 18. NB survey
    - Annex IX(I&III): *[free text – no. of certificates; of which no. of certificates issued for changes/updates to already valid MDR certificates]*
    - Annex IX(II): *[free text – no. of certificates, of which no. of certificates issued for changes/updates to already valid MDR certificates]]*
        - Of which no. of certificates requiring consultation procedure for devices incorporating medicinal substance: *[free text – no. of certificates]*
        - Of which no. of certificates requiring consultation for tissues or cells of human origin or their derivates: *[free text – no. of certificates]*
        - Of which no. of certificates requiring consultation procedure for devices based on substances or combination of substances: *[free text – no. of certificates]*
    - Annex X: *[free text – no. of certificates; of which no. of certificates issued for changes/updates to already valid MDR certificates]]*
    - Annex XI(A): *[free text – no. of certificates; of which no. of certificates issued for changes/updates to already valid MDR certificates]]*
    - Annex XI(B): *[free text – no. of certificates; of which no. of certificates issued for changes/updates to already valid MDR certificates]*

18. How many **devices** (catalogue number**) are covered by **certificates** that have already been issued under the MDR **to date** [up to 31/10/2025]? Please provide a total number as well as a breakdown per class.*

*Note: **This refers to the catalogue numbers (not individual units of the catalogue number).*

- **Total**: *[free text – number of devices referring to catalogue numbers]*

Per risk class (for all devices)

- Class Ir: *[free text – number of devices referring to catalogue numbers]*
- Class Is: *[free text – number of devices referring to catalogue numbers]*
- Class Im: *[free text – number of devices referring to catalogue numbers]*
- Class IIa: *[free text – number of devices referring to catalogue numbers]*

- Class IIb: *[free text – number of devices referring to catalogue numbers]*
- Class III: *[free text – number of devices referring to catalogue numbers]*

New devices

- Of which new devices (devices which have never been CE-marked before but will need CE-marking under the MDR to access the EU market): *[free text – number of devices referring to catalogue numbers]*
  - Of which novel devices[6]: *[free text – number of devices referring to catalogue numbers]*
  - Of which breakthrough devices[7]: *[free text – number of devices referring to catalogue numbers]*

Time periods*

19. What is the **average time taken to prepare an application for MDR[8]** (before submission to a notified body)? *[drop down]*
    - Less than 6 months
    - 6-12 months
    - 13-18 months
    - 19-24 months
    - More than 24 months
    - I don't know.

20. What is the **average timeframe between application lodged and written agreement** signed? *[drop down]* 18. NB survey
    - 1-2 weeks
    - 3-4 weeks
    - >1 to 2 months
    - >2 to 3 months
    - >3 to 6 months
    - More than 6 months

21. What is the **average time taken to reach issuance of a new certificate** (from written agreement signed to issuance) under the MDR? *[drop down]* 18. NB survey
    - Time to issue certification for devices that only need QMS certificates
      - Less than 6 months
      - 6-12 months
      - 13-18 months
      - 19-24 months
      - More than 24 months
      - I don't know.

[6] When assessing novelty, relevant dimensions of a device in which novelty and innovation can be manifest may include, but are not limited to the ones listed: procedure-related items, device-related items. Novelty in this context typically means that there is a lack of experience in regard to the safety and performance of the device or specific features of the device or related clinical procedure, and there are no similar devices or insufficient experience with similar devices to enable straightforward appraisal of its future real-world safety and performance. For more information see definition in the Commission guidance in section 2.1: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020XC0807(01)&rid=5

[7] Based on the MDCG 2025-9 Guidance on Breakthrough Devices (BtX) under Regulations 2017/745 & 2017/746, a MD or IVD will be considered a breakthrough device if it meets each of the following criteria:
1. Novelty: The device introduces a high degree of novelty with respect to the device technology, the related clinical procedure, and/or the application of the device in clinical practice,
AND
2. Positive clinical impact: The device is expected to provide a significant positive clinical impact on patients or public health, for a life-threatening or irreversibly debilitating disease or condition, by either of the following:
o Offering a significant positive clinical impact on patients or public health compared to available alternatives and the state of the art, OR
o Fulfilling an unmet medical need where there is an absence or insufficiency of available alternative options for that purpose.
For more information see MDCG 2025-9: https://health.ec.europa.eu/document/download/edca94c7-62ab-4dd5-8539-2b347bd14809_en?filename=mdcg_2025-9.pdf

[8] This does not necessarily cover full documentation needed to reach MDR certification.

- Time to issue certification for devices that need QMS and product certificates
  - Less than 6 months
  - 6-12 months
  - 13-18 months
  - 19-24 months
  - More than 24 months
  - I don't know.

22. In general, do you **comply with the deadlines agreed with your NB(s) for submitting data / information and subsequent further requests?**
    - Yes
    - No
      - If not, why?
    - I don't know.
23. Comments on the time periods - MDR: [free text; optional]

If yes to Q16.1:

Re-certification *

For QMS certificates and EU technical documentation assessment certificate (TDA) renewed under the MDR[9]

	EU technical documentation assessment (TDA) certificate	**MDR QMS certificates**
24. How many certificates are **expiring** and due for recertification in • 2026 [no.] • 2027 [no.] • 2028 [no.] • 2029 [no.]	*If you do not have the information please enter "na" or no certificates are expiring, please enter "0".*	*If you do not have the information please enter "na" or no certificates are expiring, please enter "0".*
25. On average, when do you **need to submit the information for recertification to the NB** (before the expiration of the certificate) to assure you receive the renewal before expiration?	• 3 months • 6 months • 9 months • 12 months • More than 12 months • No information available	• 3 months • 6 months • 9 months • 12 months • More than 12 months • No information available
26. What is the **average time** taken to **reach renewal of the certificate (from the submission to renewal)**?	• Less than 6 months • 6-12 months • 13-18 months • More than 18 months • No information available	• Less than 6 months • 6-12 months • 13-18 months • More than 18 months • No information available

Costs

If yes to Q16:

27. Please provide the **total cost in Euro for drawing up the clinical evaluation of the last single device certified** for each of the following, where applicable: If not available, please enter "na".

Note: please indicate it as follows: e.g.: 7000 (including all zeros, without dots or commas, no k number like 7k)

	Class I	Class Is	Class Im	Class Ir	Class IIa	Class IIb	Class IIb impl.	Class III

Total in Euro*	€	€	€	€	€	€	€	€

28. What is the **direct cost per certificate in EURO** that has already been issued under the MDR to date [31/10/2025]? *

Please enter "na" if not applicable or no answer can be provided.

- For QMS certificates:
  - total cost for initial certificate: *[free text – average cost for one certificate]*
    - How much of the total cost represents fees paid to NB? *[free text – average cost for NB fees]*
  - yearly cost for maintenance: *[free text – yearly average cost for one certificate]*
    - How much of the yearly cost represents fees paid to NB? *[free text – average cost for NB fees]*
  - **If yes to Q16.1:** total cost for renewed certificate: *[free text – average cost for one certificate]*
    - How much of the total cost represents fees paid to NB? *[free text – average cost for NB fees]*
- For product certificates:
  - total cost for initial certificate: *[free text – average cost for one certificate]*
    - How much of the total cost represents fees paid to NB? *[free text – average cost for NB fees]*
  - yearly cost for maintenance: *[free text – yearly average cost for one certificate]*
    - How much of the yearly cost represents fees paid to NB? *[free text – average cost for NB fees]*
  - **If yes to Q16.1:** total cost for renewed certificate: *[free text – average cost for one certificate]*
    - How much of the total cost represents fees paid to NB? *[free text – average cost for NB fees]*

Estimates

29. Of **your total portfolio** that requires an MDR certificate and which you plan to apply for under the MDR (portion of the certified products counted in catalogue numbers compared to the total number of devices), what percentage **has already received an MDR certificate**?* *[drop down]*
    - ≤10%
    - 11-20%
    - 21-30%
    - 31-40%
    - 41-50%
    - 51-60%
    - 61-70%
    - 71-80%
    - 81-90%
    - 91-100%

Discontinued medical devices

30. Have you **stopped the production/marketing/supply of some devices to the EU market since 2021?** *
    - Yes
      - If yes, which kind of medical devices were affected? *[free text – please indicate the relevant EMDN level 5 codes if possible] Download EMDN Code list*
      - If yes, what were the main reasons for product discontinuation? *[please select the main 3 that apply]*
        - Manufacturer recalls or safety concerns
        - Decisions/recommendations by national competent authorities
        - Products at the end of their life cycle
        - Products with low sales volumes
        - Products with low profitability
        - Devices will be replaced by updated/new products
        - Product revenue does not justify cost to reapprove device under the MDR

- Lack of raw materials and/or components
- Increased production costs
- Disruptions in the supply chain / Supplier has stopped production
- Other: *[please specify]*

- If yes, were orphan/niche devices[10] or orphan indications affected?
  - Yes
  - No
- If yes, were devices affected that you used to place on the market as an Own Brand Labelled (OBL) manufacturer?
  - Yes
  - No

- No

2.3 IVD: Questionnaire on IVDs

IVD

The questions marked with a red asterisk * are mandatory and must be completed.

IVDD – legacy devices[11]*

Purpose of these questions: to get to know how many IVDD devices (legacy devices) and valid certificates your company has (still) to date and how many of the devices will be transitioned to IVDR. It should give an indication of the expected availability of the company's medical devices on the market after transitioning to the IVDR.
**This refers to the catalogue number (not individual units of the catalogue number).

31. Total number of IVDD devices** placed on the market to date (incl. general IVDs, IVDs for self-testing, IVDs in Annex II – List A & B) [31/10/2025]: *[free text – number of IVDs referring to catalogue numbers]*

    31.1 Of this total number, please specify the percentage that you have already transferred to or plan to transition to the IVDR**[12]: *[drop down]*
    - ≤10%
    - 11-20%
    - 21-30%
    - 31-40%
    - 41-50%
    - 51-60%
    - 61-70%
    - 71-80%
    - 81-90%
    - 91-100%

[10] According to the MDCG 2024-10 document on clinical evaluation of orphan medical devices, a medical device or an accessory for a medical device should be regarded as **'orphan device'**, if it meets the following criteria: the device is specifically intended to benefit patients in the treatment, diagnosis, or prevention of a disease or condition that presents in not more than 12,000 individuals in the European Union per year; and at least one of the following criteria are met: there is insufficiency of available alternative options for the treatment, diagnosis, or prevention of this disease/condition, or the device will offer an option that will provide an expected clinical benefit compared to available alternatives or state of the art for the treatment, diagnosis, or prevention of this disease/condition, taking into account both device and patient population specific factors.

[11] In line with MDCG 2022-8, 'legacy devices' should be understood as IVDs, which, in accordance with the IVDR's transitional provisions, are placed on the market or put into service after the IVDR's date of application (i.e. 26 May 2022) if certain conditions are fulfilled.

[12] This covers three different scenarios: 1) MF has not yet submitted the application for IVDR but has the intention to do so, 2) IVDR application submitted but not finished, 3) IVDR application submitted and IVDR certificates were issued but the MF is keeping the IVDD device on the market in parallel or while the IVDR device is completing final steps like labelling preparation etc. .

31.2 Of this total number, please specify the number of IVDD devices** that will need NB intervention for the first time AND you plan to transition to the IVDR and is not IVDR certified yet: *[free text – number of IVDs referring to catalogue numbers]*

32. Total number of **valid IVDD certificates** to date [31/10/2025]: *[free text – no. of valid certificates (QMS + product certificates)]*

Notified bodies – written agreements, refused applications

Purpose of these questions: to understand how many companies have written agreements with notified bodies. Written agreements can be framework agreements with NBs (covering several applications) or contracts for each application (signed by the NB and manufacturer). This indication should help clarify how far companies are in the transition process (application – written agreement – certificates) to the IVDR and whether they could use the time in the light of the extension to the IVDR transitional period (Regulation (EU) 2024/1860).

Written agreements

33. Do you have **written agreements** with (a) notified body(ies) designated under the IVDR?* *[select one option]*

18. NB survey

- Yes, all of the devices my company would like to transition to the IVDR are covered by written agreements with one or several notified body(ies).
- Yes, but only some of the devices my company would like to transition to the IVDR are covered by a written agreement with one or several notified body(ies).
    - When do you expect that all products will be covered by a written agreement? *[free text; enter date and explanation]*
- No, my company has sent in some or all of the applications but has not signed any written agreement yet.
    - Please specify why: *[free text]*
- No, my company has not sent an application or signed any written agreement yet.
    - Please specify why: *[free text]*
- No, my current notified body(ies) has(have) not been designated under the IVDR.
- Not applicable – my devices do not need notified body involvement.

33.1 **If yes**: Which devices are covered in this/these written agreement(s)? * *[single-choice]*

- Only legacy devices
- Legacy and "new" devices (devices which have never been CE-marked but will need CE-marking under the IVDR to access the EU market)
- Only new devices

Refused applications

34. Did a notified body **refuse an application**[13] **under the IVDR**?*

- Yes
    - (optional) If yes, please indicate the average time passed since application was sent until refusal *[drop down]*
        - Less than 6 months
        - 6–12 months
        - 13–18 months
        - 19–24 months
        - more than 24 months

[13] Application = Submission for certification

- If yes, what were the reasons for the refusal?
  - Application deemed incomplete: *[no. of refused applications]*
    - Please specify reasoning of NB: [optional]
  - Wrong qualification of product/classification of device: *[no. of refused applications]*
  - Wrong conformity assessment procedure: *[no. of refused applications]*
  - Outside the scope of the notified body's designation: *[no. of refused applications]*
  - Insufficient notified body resources: *[no. of refused applications]*
  - Other: [no. of refused applications] *[free text specifying the "other" reason for refusal]*
- If yes: *[multiple choice]*
  - For legacy devices
  - For "new" devices (devices which have never been CE-marked but will need CE-marking under the IVDR to access the EU market)

- No, my company has not sent an application yet.
- No, applications were not refused so far.
- Not applicable

IVDR implementation

Purpose of these questions: to monitor the progress of the transition status of devices to the IVDR and to get an indication of the future workload for notified bodies.

Applications

35. How many **applications**** in total have you **lodged under the IVDR to your notified body(ies)** [up to 31/10/2025]?* If there are no applications or certificates for an annex, please write "0". 18. NB survey

Note:

**This number also includes applications with issued certificates, ongoing applications and applications that were ultimately refused. Please note that applications lodged for changes to existing IVDR certificates are included as well but should also be indicated separately. Pre-application activities are not included. We ask you to complete all rows.

- Annex IX(I&III): *[free text – no. of applications; of which no. of applications lodged for changes]*
- Annex IX(II): *[free text – no. of applications; of which no. of applications lodged for changes]*
- Annex X: *[free text – no. of applications; of which no. of applications lodged for changes]]*
- Annex XI: *[free text – no. of applications; of which no. of applications lodged for changes]]*
- All Annexes: Of which Class D devices: *[free text – no. of applications]*
- All **Annexes: Of which** requiring consultation for companion diagnostics: *[free text – no. of applications]*

36. How **many devices** (catalogue number**) are **undergoing the IVDR conformity assessment process** (lodged IVDR applications still under review by NB) to date [31/10/2025]? Please provide a total number as well as a breakdown per IVDR risk class.*

Note: ***This refers to the catalogue numbers (not individual units of the catalogue number).*

- Total: *[free text – number of IVDs referring to catalogue numbers]*
- Class A Sterile: *[free text – number of IVDs referring to catalogue numbers]*
- Class B: *free text – number of IVDs referring to catalogue numbers]*
- Class C: *[free text – number of IVDs referring to catalogue numbers]*
- Class D: *[free text – number of IVDs referring to catalogue numbers]*

Certificates

37. Have you already received **certificates under the IVDR** to date [up to 31/10/2025]?*

- Yes *(trigger for Q38-Q39, Q48-Q49)*
  - 37.1 If yes, did you already have a certificate renewed under the IVDR?
    - Yes (*trigger for Q45-Q47)*
    - No

- No

If yes to Q37:

38. How many **certificates** have already been issued under the IVDR by Annex for your portfolio **to date** [up to 31/10/2025]? If no certificates have been issued, please enter "0".* 18. NB survey

- Annex IX(I&III): *[free text – no. of certificates; of which no. of certificates issued for changes/updates to already valid IVDR certificates]]*
- Annex IX(II): *[free text – no. of certificates; of which no. of certificates issued for changes/updates to already valid IVDR certificates]]*
- Annex X: *[free text – no. of certificates; of which no. of certificates issued for changes/updates to already valid IVDR certificates]]*
- Annex XI: *[free text – no. of certificates; of which no. of certificates issued for changes/updates to already valid IVDR certificates]]*

39. How many **devices** (catalogue number**) are covered by **certificates** that have already been issued under the IVDR **to date** [up to 31/10/2025]? Please provide a total number as well as a breakdown per IVDR risk class.*

*Note: **This refers to the catalogue numbers (not individual units of the catalogue number).*

- Total: *[free text – number of IVDs referring to catalogue numbers]*
- Class A Sterile: *[free text – number of IVDs referring to catalogue numbers]*
- Class B: *[free text – number of IVDs referring to catalogue numbers]*
- Class C: *[free text – number of IVDs referring to catalogue numbers]*
- Class D: *[free text – number of IVDs referring to catalogue numbers]*

Time periods *

40. What is the **average time taken to prepare an application for IVDR**[14] (before submission to a notified body)? *[drop down]*

- Less than 6 months
- 6–12 months
- 13–18 months
- 19–24 months
- More than 24 months
- I don't know.

41. What is the **average timeframe between application lodged and written agreement** signed? *[drop down]* 18. NB survey
    - 1–2 weeks
    - 3–4 weeks
    - >1 to 2 months
    - >2 to 3 months
    - >3 to 6 months
    - More than 6 months
42. What is the **average time taken to reach issuance of a new certificate** (from written agreement signed to issuance) under the IVDR? *[drop down]* 18. NB survey

- Time to issue certification for devices that only need QMS certificates
    - Less than 6 months
    - 6–12 months
    - 13–18 months
    - 19–24 months

[14] This does not necessarily cover full documentation needed to reach IVDR certification.

- More than 24 months
- I don't know.

- Time to issue certification for devices that need QMS and product certificates
  - Less than 6 months
  - 6–12 months
  - 13–18 months
  - 19–24 months
  - More than 24 months
  - I don't know.

43. In general, do you comply with the deadlines agreed with your NB(s) for submitting data / information and subsequent further requests?

- Yes
- No
  - If not, why?

44. Comments on the time periods – IVDR: *[free text; optional]*

If yes to Q37.1:

Re-certification *

For QMS certificates and EU technical documentation assessment certificates (TDA) renewed under the IVDR[15]

	EU technical documentation assessment (TDA) certificate	**IVDR QMS certificates**
45. How many certificates are **expiring** and due for recertification in • 2026 [no.] • 2027 [no.] • 2028 [no.] • 2029 [no.]	*If you do not have the information, please enter "na" or no certificates are expiring, please enter "0".*	*If you do not have the information, please enter "na" or no certificates are expiring, please enter "0".*
46. On average, when do you **need to submit the information for recertification to the NB** (before the expiration of the certificate) to ensure you receive the renewal before expiration?	• 3 months • 6 months • 9 months • 12 months • More than 12 months • No information available	• 3 months • 6 months • 9 months • 12 months • More than 12 months • No information available
47. What is the **average time** taken to **reach renewal of the certificate (from the submission to renewal)**?	• Less than 6 months • 6–12 months • 13–18 months • More than 18 months • No information available	• Less than 6 months • 6–12 months • 13–18 months • More than 18 months • No information available

Costs

If yes to Q37:

48. Please provide the **total cost in Euro for drawing up the performance evaluation of the last single device certified** for each of the following, where applicable: * If not available, please enter "na".

Note: please indicate it as follows: e.g.: 7000 (including all zeros, without dots or commas, no k number like 7k)

	Class A sterile	Class B	Class C	Class D
Total in Euro	€	€	€	€

49. What is the **direct cost per certificate in EURO** that has already been issued under the IVDR to date [31/10/2025]? * Please enter "na" if not applicable or no answer can be provided.

- For QMS certificates:
  - total cost for initial certificate: *[free text – average cost for one certificate]*
    - How much of the total cost represents fees paid to NB? *[free text – average cost for NB fees]*
  - yearly cost for maintenance: *[free text – yearly average cost for one certificate]*
    - How much of the yearly cost represents fees paid to NB? *[free text – average cost for NB fees]*
  - **If yes to Q37.1:** total cost for renewed certificate: *[free text – average cost for one certificate]*
    - How much of the total cost represents fees paid to NB? *[free text – average cost for NB fees]*
- For product certificates:
  - total cost for initial certificate: *[free text – average cost for one certificate]*
    - How much of the total cost represents fees paid to NB? *[free text – average cost for NB fees]*
  - yearly cost for maintenance: *[free text – yearly average cost for one certificate]*
    - How much of the yearly cost represents fees paid to NB? *[free text – average cost for NB fees]*
  - **If yes to Q37.1:** total cost for renewed certificate: *[free text – average cost for one certificate]*
    - How much of the total cost represents fees paid to NB? *[free text – average cost for NB fees]*

Estimates

50. For how many new devices that were not in the IVDD portfolio do you plan to apply for a certificate under the IVDR?*
    - Total: *[free text – number of IVDs referring to catalogue numbers]*
    - Class A Sterile: *[free text – number of IVDs referring to catalogue numbers]*
    - Class B: *[free text – number of IVDs referring to catalogue numbers]*
    - Class C: *[free text – number of IVDs referring to catalogue numbers]*
    - Class D: *[free text – number of IVDs referring to catalogue numbers]*

Discontinued IVDs

51. Have you **stopped the production/marketing/supply of some IVDs to the EU market since 2022?** *
    - Yes
      - If yes, which kind of IVDs were affected? *[free text – please indicate the relevant EMDN level 5 codes if possible] Download EMDN Code list*
      - If yes, what were the main reasons for product discontinuation? *[please select the main 3 that apply per kind of IVD]*
        - Manufacturer recalls or safety concerns
        - Decisions/recommendations by national competent authorities
        - Products at the end of their life cycle
        - Products with low sales volumes
        - Products with low profitability
        - Devices will be replaced by updated/new products
        - Product revenue does not justify cost to reapprove device under the IVDR.
        - Lack of raw materials and/or components
        - Increased production costs
        - Disruptions in the supply chain / Supplier has stopped production
        - Other: *[please specify]*

- If yes, were orphan/niche devices[16] or orphan indications affected?
  - Yes
  - No
- If yes, were devices affected that you used to place on the market as an Own Brand Labelled (OBL) manufacturer?
  - Yes
  - No

- No

52. Do you **plan to discontinue some IVDs on the EU market in the coming months**? *

- Yes
  - If yes, which kind of IVDs will be affected? *[free text – please indicate the relevant EMDN level 5 codes] Download EMDN Code list*
  - If yes, what are the main reasons for product discontinuation? *[please select the main 3 that apply]*
    - Manufacturer recalls or safety concerns
    - Decisions/recommendations by national competent authorities
    - Products at the end of their life cycle
    - Products with low sales volumes
    - Products with low profitability
    - Devices will be replaced by updated/new products
    - Product revenue does not justify cost to reapprove device under the IVDR.
    - Lack of raw materials and/or components
    - Increased production costs
    - Disruptions in the supply chain / Supplier has stopped production
    - Other: *[please specify]*
  - If yes, will orphan/niche devices[17] or orphan indications be affected?
    - Yes
    - No
  - If yes, will Own Brand Labelled devices be affected?
    - Yes
    - No
- No

Preparedness of manufacturers

53. Do you have an **IVDR compliant QMS[18]**? * *[please tick one option]*
    - Yes
      - If yes, is it certified?
        - Yes, our QMS has been certified for the complete product portfolio.

[16] According to the MDCG 2024-10 document on clinical evaluation of orphan medical devices, a medical device or an accessory for a medical device should be regarded as **'orphan device'**, if it meets the following criteria: the device is specifically intended to benefit patients in the treatment, diagnosis, or prevention of a disease or condition that presents in not more than 12,000 individuals in the European Union per year; and at least one of the following criteria are met: there is insufficiency of available alternative options for the treatment, diagnosis, or prevention of this disease/condition, or the device will offer an option that will provide an expected clinical benefit compared to available alternatives or state of the art for the treatment, diagnosis, or prevention of this disease/condition, taking into account both device and patient population specific factors.

[17] According to the MDCG 2024-10 document on clinical evaluation of orphan medical devices, a medical device or an accessory for a medical device should be regarded as **'orphan device'**, if it meets the following criteria: the device is specifically intended to benefit patients in the treatment, diagnosis, or prevention of a disease or condition that presents in not more than 12,000 individuals in the European Union per year; and at least one of the following criteria are met: there is insufficiency of available alternative options for the treatment, diagnosis, or prevention of this disease/condition, or the device will offer an option that will provide an expected clinical benefit compared to available alternatives or state of the art for the treatment, diagnosis, or prevention of this disease/condition, taking into account both device and patient population specific factors.

[18] This refers to EU QMS certification under IVDR and not ISO 13485 accreditation.

        - Yes, our QMS has been certified at least to cover part of our product portfolio.
        - No, we operate an IVDR compliant QMS today, but it has not yet been certified.
    - No, we do not yet claim to operate an IVDR compliant QMS but have a QMS system in place which is compliant with IVDD.
    - No

54. Have you already **transferred your products/technical documentation** to the **IVDR?** *[please tick one option]*
    - Yes, our first product(s) has(have) been IVDR certified.
    - Yes, we have submitted products for IVDR certification and are progressing towards certification.
    - Yes, we have submitted products but have insufficient feedback from NBs to be confident that we will obtain IVDR certification in time.
    - No, we have not yet submitted but are confident that we will get timely certification thereafter.
    - No
    - Not applicable

2.4 AR-MD/IVD: Questionnaire for authorised representatives

AR

55. Are you an **authorised representative**: * *[single choice question]*
    a. Within the organisational structure of the legal manufacturer

    Note: Please make sure that only ONE answer per company within the same organisational structure is provided. The legal manufacturer is strongly encouraged to complete the survey part for manufacturers. Alternatively, the AR on behalf of the legal manufacturer could complete the survey (manufacturer part). The subset of questions for authorised representatives is targeted at "3rd party authorised representatives" / ARs which are not part of the organisational structure of the legal manufacturer but operate with "external clients".

    b. Not within the organisational structure of the legal manufacturer ("contract AR"; AR for manufacturers that are external clients to the AR)

56. For **how many different companies** do you act as an authorised representative? **[drop down]*
    - Fewer than 10 clients
    - Between 10 and 100 clients
    - Between 101 and 500 clients
    - More than 500 clients
    - Not applicable

57. Estimation for **legacy devices** (AIMDD/MDD/IVDD): How many of your clients have **completed the transition to the MDR or IVDR** (all devices are CE-marked)? * *[drop down]*
    - For **MDR**:
        - Fully completed:
            - Less than 25 %
            - 25-50 %
            - 51-75 %
            - More than 75 %
        - Partially completed:
            - Less than 25 %
            - 25-50 %
            - 51-75 %
            - More than 75 %

- Clients have not yet started the transition.
    - Less than 25 %
    - 25–50 %
    - 51–75 %
    - More than 75 %
- I don't know / not applicable.

- For **IVDR**:
    - Fully completed:
        - Less than 25 %
        - 25–50 %
        - 51–75 %
        - More than 75 %
    - Partially completed:
        - Less than 25 %
        - 25–50 %
        - 51–75 %
        - More than 75 %
    - Clients have not yet started the transition.
        - Less than 25 %
        - 25–50 %
        - 51–75 %
        - More than 75 %
    - I don't know / not applicable.

2.5 Closing

Any other issue

58. Is there **anything else** that you would like to share with us? Do you have any concerns or suggestions? *[free text]*
59. Would you be **interested in and available for follow-up interviews** in relation to the survey design or other input? *[yes/no]*

We thank you for your participation. We very much appreciate your input. If you have any questions about the survey or our study, please do not hesitate to contact us: medical.devices@goeg.at

If you know of any further (national) contacts or any relevant literature that could be useful for this study, please feel free to provide details. *open field: "further contacts"; open field: "relevant literature"*

Thank you very much for your participation in this survey.