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

2nd survey for MD and IVD manufacturers, authorised representatives, importers and distributors

HaDEA/2021/P3/03

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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 36 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), importers (IM) and distributors (DB).** We kindly ask all economic operators, 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 second survey round with economic operators in this study. The first survey round took place from November 2023 to January 2024. The question set in this survey is very similar to the question set in the first survey round to allow for comparability of the results to some extent. The study team is aware that between the first and this second survey round 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 European Commission is currently conducting a targeted evaluation *of the MDR and IVDR. In this context, specific questions aiming at informing the targeted evaluation were integrated in this survey. These questions are also aimed at importers and distributors.*

The results of the first survey round have been compiled and analysed by the study team and are now published: Link to the dashboard and presentation

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**.
Please note that the data set for the **targeted evaluation** is collected by the study team only once on behalf of DG SANTE. The pseudonymised raw data will be forwarded to DG SANTE for the analyses of the data.

To participate in the online survey:

https://ec.europa.eu/eusurvey/runner/2024MDAvailabilityMFARIMDBsurvey#

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.

[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)

- 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.
- 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 12. NB survey are also asked in the 12th notified body survey.
- Questions marked with Targeted evaluation will be used for the targeted evaluation.

Survey deadline: 28 February 2025 (23:59 CET)

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

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]*
   - micro (1 to 9 employees)
   - small (10 to 49 employees)

[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.

- medium (50 to 249 employees)
- large (250 or more employees)

5. **Staff**: Please indicate the number of people (counted in Full Time Equivalents (FTE)) employed on 31/10/2024 by your organisation for regulatory compliance with MDR/IVDR (only internal staff): * Targeted evaluation

   [total no. in FTE]

   [optional] Comments regarding staff: *[free text]*

6. 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

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 [31/10/2024]? 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**)*
- Importer (IM) *(trigger for survey **IM**)*
- Distributor (DB) *(trigger for survey **DB**)*

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** [31/10/2024]: *[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 [31/10/2024]: *[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]*

    12. 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 31/10/2024]?* If there are no applications for an Annex, please write "0". 12. 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 [31/10/2024]? 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 31/10/2024]? *
    - Yes *(trigger for Q17-Q23; Q29- Q31)*
    - No

17. How many **certificates** have already been issued under the MDR by Annex for your portfolio **to date** [up to 31/10/2024]? If no certificates have been issued, please enter "0".* 12. 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 31/10/2024]? 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]*

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]*

[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

- Of which breakthrough devices[7]: *[free text – number of devices referring to catalogue numbers]*

Per risk class

- 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]*

Recertification *

For QMS certificates and EU technical documentation assessment certificate (TDA) renewed under the MDR[8]

	EU technical documentation assessment (TDA) certificate	**MDR QMS certificates**
19. How many certificates are **expiring** and due for recertification in • 2024 [no.] • 2025 [no.] • 2026 [no.] • 2027 [no.] • 2028 [no.] *If you do not have the information or no certificates are expiring, please enter "0".*		
20. Did you already have a **certificate renewed under the MDR**?	• Yes/No • If yes, how many did you have on 31/10/2024?	• Yes/No • If yes, how many did you have on 31/10/2024?
21. 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
22. What is the **average time** taken to **prepare a recertification dossier (before submission)?**	• Less than 6 months • 6–12 months • 13–18 months • No information available	• Less than 6 months • 6–12 months • 13–18 months • No information available

[7] For the purpose of this survey, a medical device or IVD will be considered a breakthrough medical device or IVD (BTxMD or BTxIVD) if it meets the following criteria:
• Unmet Need: The device is intended for use in the treatment, diagnosis, or prevention of life-threatening or irreversibly debilitating conditions, and there are no alternative therapies or current options are significantly inferior. The device demonstrates potential to address a critical public health need, reduce morbidity, or drastically improve clinical outcomes for patients.
• Clinical Benefit: The device offers substantial improvements in patient outcomes compared to existing solutions, in terms of clinical effectiveness, safety, or quality of life.
• Innovative Design or Technology: The device incorporates a novel technology, such as AI, robotics, or next-generation diagnostics, that is not yet widely available on the market.

[8] Type-examination certificates are excluded in this survey due to the low number of Annex X certificates issued till end of October 2024.

23. 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 • No information available	• Less than 6 months • 6–12 months • 13–18 months • No information available

Time periods*

24. What is the **average time taken to prepare an application for MDR[9]** (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.

24.1. Which device risk classes are included in this average calculation? *[Please tick all that apply – multiple choice]*
    - Class Ir
    - Class Is
    - Class Im
    - Class IIa
    - Class IIb
    - Class III

25. What is the **average timeframe between application lodged and written agreement** signed? *[drop down]* 12. NB survey
    - 1–2 weeks
    - 3–4 weeks
    - >1 to 2 months
    - >2 to 3 months
    - >3 to 6 months
    - More than 6 months

26. What is the **average time taken to reach issuance of a new certificate** (from written agreement signed to issuance) under the MDR? *[drop down]* 12. 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.
    - 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.

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

27. Of the indicated time to reach issuance of a new MDR certificate (*from written agreement signed to issuance*), please provide an **estimation of the total time to achieve certification between notified body and manufacturer.***

- Time with the notified body (e.g. for checking the documents including application and technical documentation): *[percentage]*
- Time with the manufacturer (e.g. for revising the documents including application and technical documentation): *[percentage]*

Note: The sum of the percentages must result in 100%.

28. Comments on the time periods – MDR: [free text; optional]

Costs

Targeted evaluation

(only to be answered if Q16 = "yes")

29. 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 applicable, please enter "0".

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*	€	€	€	€	€	€	€	€
Thereof % adjustment costs[10] (optional)	%	%	%	%	%	%	%	%
Thereof % administrative cost[11] (optional)	%	%	%	%	%	%	%	%
Thereof % enforcement cost[12] (optional)	%	%	%	%	%	%	%	%

30. What were the **costs for certificates per MDR Annex**? *

In this section you will be asked to indicate the **costs for the first and last certificate** your company has obtained **under each Annex** in the timeframe of **01/01/2022-31/10/2024**.

Please select the applicable Annexes:

- QMS certificates
  - Not applicable because no QMS certificate has yet been received.
  - Annex IX (I+III)
  - Annex XI Part A
- Product certificates
  - Not applicable because no product certificate has yet been received.

[10] Adjustment costs: are direct compliance costs other than administrative costs and charges (see footnote 11). These are incremental investments and expenses that your organisation had to bear in order to comply and adjust its activity to the requirements contained in a legal rule (examples: direct labor costs, overheads, equipment costs, material costs, etc).

[11] Administrative costs are another type of direct compliance costs. These are borne by your organisation as a result of administrative activities performed to comply with administrative obligations included in legal rules. (examples: labelling, reporting, registration, provision of data as well as monitoring and assessments needed to generate information).

[12] Enforcement cost: costs associated with activities linked to the implementation of an initiative such as monitoring, inspections and adjudication/litigation. (examples: dealing with queries and applications, handling complaints, etc)

- Annex IX(II)
- Annex X
- Annex XI Part B

Overview of requested data

Annex	Requested MDR certificate	Requested information
QMS certificates		

Annex IX(I+III)
Annex XI Part A
	Last certificate issued AND First certificate issued between 01/01/2022-31/10/2024	**On the certificate**
		• Date of the certificate [DD.MM.YY]
		• Is this the first certificate your organisation has obtained under this Annex? *[yes/no]*
		• How many devices (counted in catalogue numbers) were included in the certificate by risk class? *[Class Is, Class Im, Class Ir, Class IIa, Class IIb, Class IIb impl., Class III]*
		• Please indicate which of the following apply to the certificate, if any:
		  • Includes medicines & human blood derivatives
		  • Includes human tissue
		  • Includes animal tissue
		  • Includes biological substances
		  • Includes machinery
		  • Includes devices composed of substances or of a combination of substances
		  • Includes nanomaterials
		  • Includes biological coating/absorbed
		  • Includes software
		  • Includes procedure packs
		  • Includes no medical purpose
		  • Includes class III custom made implant
		  • Includes incorporation of an IVD
		  • None of the indicated
		  • Others: *[please specify]*
		Costs:
		Note: please indicate it as follows: e.g.: 7000 (including all zeros, without dots or commas, no k number like 7k)
		• What was the total cost for obtaining the certificate[13]? *[free text, Euro]*
		• Did you hire an external consultant to carry out any of the tasks for obtaining the certificate? *[yes/no]*
		  • If yes, what tasks did you employ the consultant for?
		  • Identification of qualification and classification of the device
		  • Full technical documentation
		  • Pre-clinical evaluation
		  • Clinical evaluation
		  • Risk management
		  • Establishment of QMS
		  • Labelling and instruction for use
		  • Strategic work
		  • Other: *[please specify]*
		  • If yes, how much of the total cost represents payments to the consultant for the work carried out? *[free text, Euro]*
		• How much of the total cost represents fees paid to NBs? *[free text, Euro}*
		• Where applicable, please estimate what percentage of the total cost applies to the following cost categories: [optional]
		  • adjustment costs: *[% of total cost]*
		  • administrative cost: *[% of total cost]*

[13] All costs, including staff, fees to NBs, any other fees to CAs, horizontal costs, etc.daje

			• enforcement cost: *[% of total cost]* ***Additional questions for the <u>first</u> certificate on the maintenance costs:*** • What was the yearly average cost for maintenance of the certificate? *[free text, Euro]* • Did you hire an external consultant to carry out any of the tasks for the maintenance of the certificate? *[yes/no]* • If yes, how much of the yearly average cost for maintenance represents payments to the consultant for the work carried out? *[free text, Euro]* • How much of the yearly average cost for maintenance represents fees paid to NBs? *[free text, Euro]* • Where applicable, please estimate what percentage of the average yearly cost for maintenance applies to the following cost categories: [optional] • adjustment costs: *[% of total cost]* • administrative cost: *[% of total cost]* • enforcement cost: *[% of total cost]*
	Product certificates		
	Annex IX(II) Annex X Annex XI Part B	Last certificate issued *AND* First certificate issued between 01/01/2022-31/10/2024	**On the certificate** • Date of the certificate [DD.MM.YY] • Is this the first certificate your organisation has obtained under this Annex? *[yes/no]* • How many devices (counted in catalogue numbers) were included in the certificate by risk class? *[Class Is, Class Im, Class Ir, Class IIa, Class IIb, Class IIb impl., Class III]* • Please indicate which of the following apply to the certificate, if any: • Includes medicines & human blood derivatives • Includes human tissue • Includes animal tissue • Includes biological substances • Includes machinery • Includes devices composed of substances or of a combination of substances • Includes nanomaterials • Includes biological coating/absorbed • Includes software • Includes procedure packs • Includes no medical purpose • Includes class III custom made implant • Includes incorporation of an IVD • None of the indicated • Others: *[please specify]* **Costs:** Note: please indicate it as follows: e.g.: 7000 (including all zeros, without dots or commas, no k number like 7k) • What was the total cost for obtaining the certificate[14]? *[free text, Euro]* • Did you hire an external consultant to carry out any of the tasks for obtaining the certificate? *[yes/no]* • If yes, what tasks did you employ the consultant for? • Identification of qualification and classification of the device • Full technical documentation • Pre-clinical evaluation • Clinical evaluation • Risk management • Establishment of QMS • Labelling and instruction for use • Strategic work

[14] All costs, including staff, fees to NBs, any other fees to CAs, horizontal costs, etc.

		• Other: *[please specify]* • If yes, how much of the total cost represents payments to the consultant for the work carried out? *[free text, Euro]* • How much of the total cost represents fees paid to NBs? *[free text, Euro}* • Where applicable, please estimate what percentage of the total cost applies to the following cost categories: [optional] • adjustment costs: *[% of total cost]* • administrative cost: *[% of total cost]* • enforcement cost: *[% of total cost]* ***Additional questions for the <u>first</u> certificate on the maintenance costs:*** • What was the yearly average cost for maintenance of the certificate? *[free text, Euro]* • Did you hire an external consultant to carry out any of the tasks for the maintenance of the certificate? *[yes/no]* • If yes, how much of the yearly average cost for maintenance represents payments to the consultant for the work carried out? *[free text, Euro]* • How much of the yearly average cost for maintenance represents fees paid to NBs? *[free text, Euro]* • Where applicable, please estimate what percentage of the average yearly cost for maintenance applies to the following cost categories: [optional] • adjustment costs: *[% of total cost]* • administrative cost: *[% of total cost]* • enforcement cost: *[% of total cost]*

31. Cost of recertification *

If you do not have the information, please enter "0".

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

a) Costs of the last renewed certificate issued in EURO (If you do not have a certificate renewed, please go to question b) in this section.)		
Product certificates (Annex IX(II), Annex X, Annex XI Part B)	Last certificate issued between 01/01/2022-31/10/2024	○ total cost for recertification: *[free text – cost for the last certificate]* ▪ NB cost: *[free text – cost for the last certificate]* ▪ Internal manufacturer cost: *[free text – cost for the last certificate]* ○ yearly cost for maintenance: *[free text – yearly cost for the last certificate]*
QMS certificates (Annex IX(I+III), Annex XI Part A)	Last certificate issued between 01/01/2022-31/10/2024	○ total cost for recertification: *[free text – cost for the last certificate]* ▪ NB cost: *[free text – cost for the last certificate]* ▪ Internal manufacturer cost: *[free text – cost for the last certificate]* ○ yearly cost for maintenance: *[free text – yearly cost for the last certificate]*
b) If you do not yet have a certificate re- issued, what are the estimated costs in EURO based on your current information?		
Product certificates (Annex IX(II), Annex X, Annex XI Part B)	Average estimated cost for one certificate	○ total cost for recertification: *[free text – average cost for one certificate]* ▪ NB cost: *[free text – average cost for one certificate]* ▪ Internal manufacturer cost: *[free text – aveage cost for one certificate]* ○ yearly cost for maintenance: *[free text – yearly average cost for one certificate]*
QMS certificates (Annex IX(I+III), Annex XI Part A)	Average estimated cost for one certificate	○ total cost for recertification: *[free text – average cost for one certificate]* ▪ NB cost: *[free text – average cost for one certificate]*

		▪ Internal manufacturer cost: *[free text – average cost for one certificate]* yearly cost for maintenance: *[free text – yearly average cost for one certificate]*

Estimates

32. 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

33. 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[15] or orphan indications affected?
            - Yes
            - No

[15] 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.

- If yes, were devices affected that you used to place on the market as an Own Brand Labelled (OBL) manufacturer?
  - Yes
  - No
- No

Preparedness of manufacturers

34. Did the **revised transitional periods** for MDR (Regulation (EU) 2023/607) **have an impact** on your company's decisions to transfer your product portfolio to MDR? (i.e. in general allowing more products to be transitioned) * *[yes/no]*
    - Yes.
    - No.
    - Comments (optional)

Other questions for the targeted evaluation*

Targeted evaluation

35. What is the total number of **clinical investigation reports and summaries** that you have produced? *[free text]*
36. How many of these are publicly available? *[free text]*
37. What is the total number of **summaries of clinical safety and performance** you have produced? *[free text]*
38. How many of these are publicly available? *[free text]*
39. Please indicate the **number of field safety corrective actions under the MDR** that were initiated following the review/intervention of a national competent authority [until 31/10/2024]? *[free text]*

2.3 IVD: Questionnaire on IVDs

IVD

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

IVDD – legacy devices[16]*

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).

40. 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) [31/10/2024]: *[free text – number of IVDs referring to catalogue numbers]*

    40.1 Of this total number, please specify the percentage that you have already transferred to or plan to transition to the IVDR**[17]: *[drop down]*
    - ≤10%
    - 11-20%
    - 21-30%

[16] 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.

[17] 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. .

- 31-40%
- 41-50%
- 51-60%
- 61-70%
- 71-80%
- 81-90%
- 91-100%

40.2 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]*

41. Total number of **valid IVDD certificates** to date [31/10/2024]: *[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

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

12. 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.

42.1 **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

43. Did a notified body **refuse an application[18] under the IVDR**?*

- Yes

[18] Application = Submission for certification

- (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: [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

44. How many **applications**** in total have you **lodged under the IVDR to your notified body(ies)** [up to 31/10/2024]?* If there are no applications or certificates for an annex, please write "0". 12. 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]*

45. How **many devices** (catalogue number**) are **undergoing the IVDR conformity assessment process** (lodged IVDR applications still under review by NB) to date [31/10/2024]? 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 – percentage of total]*
- Class B: *free text – percentage of total]*
- Class C: *[free text – percentage of total]*
- Class D: *[free text – percentage of total]*

Certificates

46. Have you already received **certificates under the IVDR** to date [up to 31/10/2024]?*
- Yes *(trigger for Q47-Q53; Q59- Q61)*
- No

47. How many **certificates** have already been issued under the IVDR by Annex for your portfolio **to date** [up to 31/10/2024]? If no certificates have been issued, please enter "0".* 12. 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]]*

48. How many **devices** (catalogue number**) are covered by **certificates** that have already been issued under the IVDR **to date** [up to 31/10/2024]? 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 – percentage of total]*
- Class B: *[free text – percentage of total]*
- Class C: *[free text – percentage of total]*
- Class D: *[free text – percentage of total]*

Recertification *

For QMS certificates and EU technical documentation assessment certificates (TDA) renewed under the IVDR[19]

	EU technical documentation assessment (TDA) certificate	**IVDR QMS certificates**
49. How many certificates are **expiring** and due for recertification in • 2024 [no.] • 2025 [no.] • 2026 [no.] • 2027 [no.] • 2028 [no.] If you do not have the information or no certificates are expiring, please enter "0".		
50. Did you already have a **certificate renewed under the IVDR**?	• Yes/No • If yes, how many did you have on 31/10/2024?	• Yes/No • If yes, how many did you have on 31/10/2024?
51. On average, when do you **need to submit the information for**	• 3 months • 6 months	• 3 months • 6 months

[19] Type-examination certificates are excluded in this survey as no Annex X certificates were issued till end of October 2024 by NBs.

recertification to the NB (before the expiration of the certificate) to assure you receive the renewal before expiration?	• 9 months • 12 months • More than 12 months • No information available	• 9 months • 12 months • More than 12 months • No information available
52. What is the **average time** taken to **prepare a recertification dossier (before submission)?**	• Less than 6 months • 6–12 months • 13–18 months • No information available	• Less than 6 months • 6–12 months • 13–18 months • No information available
53. 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 • No information available	• Less than 6 months • 6–12 months • 13–18 months • No information available

Time periods *

54. What is the **average time taken to prepare an application for IVDR**[20] (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.

54.1. Which device risk classes are included in this average calculation? *[Please tick all that apply – multiple choice]*

- Class A Sterile
- Class B
- Class C
- Class D

55. What is the **average timeframe between application lodged and written agreement** signed? *[drop down]* 12. NB survey

  - 1–2 weeks
  - 3–4 weeks
  - >1 to 2 months
  - >2 to 3 months
  - >3 to 6 months
  - More than 6 months

56. What is the **average time taken to reach issuance of a new certificate** (from written agreement signed to issuance) under the IVDR? *[drop down]* 12. 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.
- Time to issue certification for devices that need QMS and product certificates
  - Less than 6 months

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

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

57. Of the indicated time to reach issuance of a new IVDR certificate (*from written agreement signed to issuance*), please provide an **estimation** of the total time to achieve certification between notified body and manufacturer.*

- Time with the notified body (e.g. for checking the documents including application and technical documentation): *[percentage]*
- Time with the manufacturer (e.g. for revising the documents including application and technical documentation): *[percentage]*

Note: The sum of the percentages must result in 100%.

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

Costs

Targeted evaluation

(only to be answered if Q46 = "yes")

59. 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 applicable, please enter "0".

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	€	€	€	€
Thereof % adjustment costs[21] (optional)	%	%	%	%
Therof % administrative cost[22](optional)	%	%	%	%
Thereof % enforcement cost[23] (optional)	%	%	%	%

60. What were the **costs for certificates per IVDR Annex**? *

In this section you will be asked to indicate the **costs for the first and last certificate** your company has obtained **under each Annex** in the timeframe of **01/01/2022–31/10/2024**.

Please select the applicable Annexes:

QMS certificates

- Not applicable because no QMS certificate has yet been received.
- Annex IX (I+III)
- Annex XI

Product certificates

- Not applicable because no product certificate has yet been received.
- Annex IX(II)
- Annex X

[21] Adjustment costs: are direct compliance costs other than administrative costs and charges (see footnote 11). These are incremental investments and expenses that your organisation had to bear in order to comply and adjust its activity to the requirements contained in a legal rule (examples: direct labor costs, overheads, equipment costs, material costs, etc.).

[22] Administrative costs are another type of direct compliance costs. These are borne by your organisation as a result of administrative activities performed to comply with administrative obligations included in legal rules (examples: labelling, reporting, registration, provision of data as well as monitoring and assessments needed to generate information).

[23] Enforcement cost: costs associated with activities linked to the implementation of an initiative such as monitoring, inspections and adjudication/litigation (examples: dealing with queries and applications, handling complaints, etc.).

Overview of requested data

Annex	Requested IVDR certificate	Requested information
QMS certificates		

Annex IX(I+III)
Annex XI
	Last certificate issued
	AND
	First certificate issued between 01/01/2022-31/10/2024
	
	Also with the option for:
	Only one certificate received
	And I don't know
		On the certificate
		• Date of the certificate [DD.MM.YY]
		• Is this the first certificate your organisation has obtained under this Annex? *[yes/no]*
		• How many devices (counted in catalogue numbers) were included in the certificate by risk class? *[Class A sterile, Class B, Class C, Class D]*
		• Please indicate which of the following apply to the certificate, if any:
		  • Includes near patient test
		  • Includes self-test
		  • Includes companion diagnostic
		  • Includes instruments, equipment, systems
		  • Includes software for analysis, monitoring
		  • Includes device controlled by software
		  • None of the above
		  • Others: *[please specify]*
		Costs:
		Note: please indicate it as follows: e.g.: 7000 (including all zeros, without dots or commas, no k number like 7k)
		• What was the total cost for obtaining the certificate[24]? *[free text, Euro]*
		• Did you hire an external consultant to carry out any of the tasks for obtaining the certificate? *[yes/no]*
		  • If yes, what tasks did you employ the consultant for?
		  • Identification of qualification and classification of the device
		  • Full technical documentation
		  • Scientific validity and/or analytical performance
		  • Clinical/performance evaluation
		  • Risk management
		  • Establishment of QMS
		  • Labelling and instruction for use
		  • Strategic work
		  • Other: *[please specify]*
		  • If yes, how much of the total cost represents payments to the consultant for the work carried out? *[free text, Euro]*
		• How much of the total cost represents fees paid to NBs? *[free text, Euro}*
		• Where applicable, please estimate what percentage of the total cost applies to the following cost categories: [optional]
		  • adjustment costs: *[% of total cost]*
		  • administrative cost: *[% of total cost]*
		  • enforcement cost: *[% of total cost]*
		Additional questions for the <u>first</u> certificate on the change management of the certificate:
		• What was the yearly average cost for change management of the certificate? *[free text, Euro]*
		• Did you hire an external consultant to carry out any of the tasks for the change management of the certificate? *[yes/no]*
		  • If yes, how much of the yearly average cost for change management represents payments to the consultant for the work carried out? *[free text, Euro]*
		• How much of the yearly average cost for change management represents fees paid to NBs? *[free text, Euro]*

[24] All costs, including staff, fees to NBs, any other fees to CAs, horizontal costs, etc.

			• Where applicable, please estimate what percentage of the average yearly cost for change management applies to the following cost categories: [optional]
			  • adjustment costs: *[% of total cost]*
			  • administrative cost: *[% of total cost]*
			  • enforcement cost: *[% of total cost]*

	Product certificates		

	Annex IX(II)
	Annex X
		Last certificate issued
		AND
		First certificate issued between 01/01/2022-31/10/2024
			On the certificate
			• Date of the certificate [DD.MM.YY]
			• Is this the first certificate your organisation has obtained under this Annex? *[yes/no]*
			• How many devices (counted in catalogue numbers) were included in the certificate by risk class? *[Class A sterile, Class B, Class C, Class D]*
			• Please indicate which of the following apply to the certificate, if any:
			  • Common specifications available
			  • EURL designated in the scope
			  • Includes near patient test
			  • Includes self-test
			  • Includes companion diagnostic
			  • Includes instruments, equipment, systems
			  • Includes software for analysis, monitoring
			  • Includes device controlled by software
			  • None of the above
			  • Others: *[please specify]*
			Costs:
			Note: please indicate it as follows: e.g.: 7000 (including all zeros, without dots or commas, no k number like 7k)
			• What was the total cost for obtaining the certificate[25]? *[free text, Euro]*
			• Did you hire an external consultant to carry out any of the tasks for obtaining the certificate? *[yes/no]*
			  • If yes, what tasks did you employ the consultant for?
			  • Identification of qualification and classification of the device
			  • Full technical documentation
			  • Scientific validity and/or analytical performance
			  • Clinical/performance evaluation
			  • Risk management
			  • Establishment of QMS
			  • Labelling and instruction for use
			  • Strategic work
			  • Other: *[please specify]*
			• If yes, how much of the total cost represents payments to the consultant for the work carried out? *[free text, Euro]*
			• How much of the total cost represents fees paid to NBs? *[free text, Euro}*
			• Where applicable, please estimate what percentage of the total cost applies to the following cost categories: [optional]
			  • adjustment costs: *[% of total cost]*
			  • administrative cost: *[% of total cost]*
			  • enforcement cost: *[% of total cost]*
			Additional questions for the <u>first</u> certificate on the change management of the certificate:
			• What was the yearly average cost for change management of the certificate? *[free text, Euro]*
			• Did you hire an external consultant to carry out any of the tasks for the change management of the certificate? *[yes/no]*

[25] All costs, including staff, fees to NBs, any other fees to CAs, horizontal costs, etc.

		• If yes, how much of the yearly average cost for change management represents payments to the consultant for the work carried out? *[free text, Euro]*
		• How much of the yearly average cost for change management represents fees paid to NBs? *[free text, Euro]*
		• Where applicable, please estimate what percentage of the average yearly cost for change management applies to the following cost categories: [optional]
		  • adjustment costs: *[% of total cost]*
		  • administrative cost: *[% of total cost]*
		  • enforcement cost: *[% of total cost]*

61. Cost of recertification*

If you do not have the information, please enter "0".

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

a) Costs of the last renewed certificate issued in EURO (If you do not have a certificate renewed, please go to question b) in this section.)		
Product certificates (Annex IX(II), Annex X)	Last certificate issued between 01/01/2022-31/10/2024	○ total cost for recertification: *[free text – cost for the last certificate]* ▪ NB cost: *[free text – cost for the last certificate]* ▪ Internal manufacturer cost: *[free text – cost for the last certificate]* ○ yearly cost for maintenance: *[free text – yearly cost for the last certificate]*
QMS certificates (Annex IX(I+III), Annex XI)	Last certificate issued between 01/01/2022-31/10/2024	○ total cost for recertification: *[free text – cost for the last certificate]* ▪ NB cost: *[free text – cost for the last certificate]* ▪ Internal manufacturer cost: *[free text – cost for the last certificate]* ○ yearly cost for maintenance: *[free text – yearly cost for the last certificate]*
b) If you do not yet have a certificate re- issued, what are the estimated costs in EURO based on your current information?		
Product certificates (Annex IX(II), Annex X,	Average estimated cost for one certificate	○ total cost for recertification: *[free text – average cost for one certificate]* ▪ NB cost: *[free text – average cost for one certificate]* ▪ Internal manufacturer cost: *[free text – aveage cost for one certificate]* ○ yearly cost for maintenance: *[free text – yearly average cost for one certificate]*
QMS certificates (Annex IX(I+III), Annex XI)	Average estimated cost for one certificate	○ total cost for recertification: *[free text – average cost for one certificate]* ▪ NB cost: *[free text – average cost for one certificate]* ▪ Internal manufacturer cost: *[free text – average cost for one certificate]* yearly cost for maintenance: *[free text – yearly average cost for one certificate]*

Estimates

62. Please indicate/estimate the number of IVDs (referring to catalogue numbers):

	Total	Class A	Class A sterile	Class B	Class C	Class D
Total no. of devices included in the	*[free text – number of IVDs*	*[free text – number*	*[free text – number*	*[free text – number of*	*[free text – number*	*[free text – number of IVDs*

product portfolio (number of IVDs referring to catalogue numbers) to date [31/10/24]	*referring to catalogue numbers]*	*of IVDs referring to catalogue numbers]*	*of IVDs referring to catalogue numbers]*	*IVDs referring to catalogue numbers]*	*of IVDs referring to catalogue numbers]*	*referring to catalogue numbers]*
– Thereof no. of devices requiring IVDR certification by NBs (Class As, B, C, D)	*[free text – number of IVDs referring to catalogue numbers]*	–	*[free text – number of IVDs referring to catalogue numbers]*	*[free text – number of IVDs referring to catalogue numbers]*	*[free text – number of IVDs referring to catalogue numbers]*	*[free text – number of IVDs referring to catalogue numbers]*
– Thereof no. of devices planned to be transitioned	*[free text – number of IVDs referring to catalogue numbers]*	–	*[free text – number of IVDs referring to catalogue numbers]*	*[free text – number of IVDs referring to catalogue numbers]*	*[free text – number of IVDs referring to catalogue numbers]*	*[free text – number of IVDs referring to catalogue numbers]*
– Thereof no. of devices included in already lodged applications	*[free text – number of IVDs referring to catalogue numbers]*	–	*[free text – number of IVDs referring to catalogue numbers]*	*[free text – number of IVDs referring to catalogue numbers]*	*[free text – number of IVDs referring to catalogue numbers]*	*[free text – number of IVDs referring to catalogue numbers]*
– Thereof no. of devices included in already issued certificates	*free text – number of IVDs referring to catalogue numbers]*	–	*[free text – number of IVDs referring to catalogue numbers]*	*[free text – number of IVDs referring to catalogue numbers]*	*[free text – number of IVDs referring to catalogue numbers]*	*[free text – number of IVDs referring to catalogue numbers]*
– Thereof no. of devices not planned to be transitioned (i.e. they will be discontinued to the Union market)	*[free text – number of IVDs referring to catalogue numbers]*	–	*[free text – number of IVDs referring to catalogue numbers]*	*[free text – number of IVDs referring to catalogue numbers]*	*[free text – number of IVDs referring to catalogue numbers]*	*[free text – number of IVDs referring to catalogue numbers]*
For how many new devices that were not in the IVDD portfolio do you plan to apply for a certificate under the IVDR?	*[free text – number of IVDs referring to catalogue numbers]*	–	*[free text – number of IVDs referring to catalogue numbers]*	*[free text – number of IVDs referring to catalogue numbers]*	*[free text – number of IVDs referring to catalogue numbers]*	*[free text – number of IVDs referring to catalogue numbers]*

Discontinued IVDs

63. 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[26] 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

64. 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[27] or orphan indications be affected?
        - Yes
        - No
    - If yes, will Own Brand Labelled devices be affected?
        - Yes
        - No
- No

[26] 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.

[27] 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.

Preparedness of manufacturers

65. Do you have an **IVDR compliant QMS**[28]? * *[please tick one option]*
    - Yes
        - If yes, is it certified?
            - Yes, our QMS has been certified for the complete product portfolio.
            - 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
66. 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
67. Did the revised transitional periods for IVDR (Regulation (EU) 2024/1860) have an impact on your company's decisions to transfer your product portfolio to IVDR? (i.e. in general allowing more products to be transitioned)*
    - Yes
    - No
    - Comments (optional): *[free text]*

Other questions for the targeted evaluation*

Targeted evaluation

68. What is the total number of **performance studies reports and summaries** that you have produced? *[free text]*
69. How many of these are publicly available? *[free text]*
70. What is the total number of **summary of safety and performance** you have produced? *[free text]*
71. How many of these are publicly available? *[free text]*
72. Please indicate the **number of field safety corrective actions** under the IVDR that were initiated following the review/intervention of national competent authority [until 31 October 2024]? *[free text]*

2.4 AR-MD/IVD: Questionnaire for authorised representatives

AR

73. 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

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

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)

74. 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

75. 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 IM-MD/IVD: Questionnaire for importers

IM

Targeted evaluation

76. Please indicate the **number of devices (counted in product catalogue numbers) your organisation has imported** in the last year: *[single-choice]*
    - 1-500
    - 500-1000
    - 1000-2000
    - 2000-5000
    - 5000-10000
    - More than 10000
77. What is the **average yearly cost** in Euro related to the compliance with the general obligation for importers set out in Art. 13 and 14 respectively of the MDR/IVDR? *[free text, Euro]*

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

- Of this cost, what is the percentage of the cost related to adding information to the device? *[free text, %]*

2.6 IM-MD/IVD: Questionnaire for distributors

DB

Targeted evaluation

78. Please indicate **the number of devices (counted in product catalogue numbers) your organisation has distributed** in the last year: *[single-choice]*
    - 1-500
    - 500-1000
    - 1000-2000
    - 2000-5000
    - 5000-10000
    - More than 10000
79. What is the **average yearly cost** in Euro related to the compliance with the general obligation for distributors set out in Art. 13 and 14 respectively of the MDR/IVDR? *[free text, Euro]*

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

- Of this cost, what is the percentage of the cost related to adding information to the device? *[free text, %]*

2.7 Closing

Any other issue

80. Is there **anything else** that you would like to share with us? Do you have any concerns or suggestions? *[free text]*
81. 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.