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

Surveys for MD and IVD manufacturers and authorised representatives

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 planned 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 of medical device and *in vitro* diagnostics as well as from authorised representatives (AR).** We kindly ask all manufacturers and authorised representatives, as well as manufacturers and ARs for MDR and IVDR compliant devices that are planned to be placed on the market in the next two years, to respond to the 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 fed into a **public dashboard** and will be analysed in the form of synopsis reports.

Participation in the online survey: https://ec.europa.eu/eusurvey/runner/MFandAR

We hope to reach as many manufacturers and authorised representatives as possible and intend to keep the workload for completing the survey to a minimum.

Please note that this is a **recurring survey** and changes in scopes and quantity of questions might become necessary in the future.

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 arrow 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 advise to save the progress made 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.
- 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

Survey deadline: 15 January 2024 (23:59 CET)

[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)

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 (Q1a,b,c) 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 lead Friederike Windisch (medical.devices@goeg.at).

Acronyms used:

AIMDD = Active Implantable Medical Device Directive

AR = Authorised Representative

CER = Clinical Evaluation Report

EMDN = European Medical Device Nomenclature

EU = European Union

IFU = Instructions for Use

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 have to be completed.

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. Since it is a recurring survey further invitations to participate may be sent directly to the email address provided.

   a. **Name** of the **company**: *[free text]*
   b. **Name of the person** completing the **survey**: *[first name and surname]*
   c. **Contact details:**
      i. e-mail address: *[free text]*
      ii. 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 EU Member State is/are your authorised representative(s) based? *[List of EU-27 Member States 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.
      i. [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.
      i. [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. No, but the contracted authorised representative is registered.
      i. [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]*
   d. 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)
   - medium (50 to 249 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.

- large (250 or more employees)

5. 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 all continents)*
   - Products are not available yet.

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

6. Which **device areas** (EMDN categories) are currently included in your **product portfolio**? Please select the relevant EMDN categories and add the **total number of devices** placed on the EU market to date. (optional response)
   [multiple choice to select relevant EMDN categories and total number of devices placed on the EU market to date]

Notes: - The **total number of devices** refers to the **catalogue numbers** (not individual units of the catalogue number) – no matter whether CE-marked under AIMDD/MDD/IVDD or MDR/IVDR. - 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 and indicate the numbers. - *Purpose of this question*: to learn which and how many different 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; to better understand the bandwidth of the product portfolio – also in relation to MDR/IVDR requirements.

   - A – DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION: *[free text – number of devices referring to catalogue numbers]*
   - B – HAEMATOLOGY AND HAEMOTRANSFUSION DEVICES: *[free text – number of devices referring to catalogue numbers]*
   - C – CARDIOCIRCULATORY SYSTEM DEVICES: *[free text – number of devices referring to catalogue numbers]*
   - D – DISINFECTANTS, ANTISEPTICS, STERILISING AGENTS AND DETERGENTS FOR MEDICAL DEVICES: *[free text – number of devices referring to catalogue numbers]*
   - F – DIALYSIS DEVICES: *[free text – number of devices referring to catalogue numbers]*
   - G – GASTROINTESTINAL DEVICES: *[free text – number of devices referring to catalogue numbers]*
   - H – SUTURE DEVICES: *[free text – number of devices referring to catalogue numbers]*
   - J – ACTIVE-IMPLANTABLE DEVICES: *[free text – number of devices referring to catalogue numbers]*
   - K– ENDOTHERAPY AND ELECTROSURGICAL DEVICES: *[free text – number of devices referring to catalogue numbers]*
   - L – REUSABLE SURGICAL INSTRUMENTS: *[free text – number of devices referring to catalogue numbers]*
   - M – DEVICES FOR GENERAL AND SPECIALIST DRESSINGS: *[free text – number of devices referring to catalogue number]*
   - N – NERVOUS AND MEDULLARY SYSTEMS DEVICES: *[free text – number of devices referring to catalogue number]*
   - P – IMPLANTABLE PROSTHETIC AND OSTEOSYNTHESIS DEVICES: *[free text – number of devices referring to catalogue number]*
   - Q – DENTAL, OPHTHALMOLOGIC AND ENT DEVICES: *[free text – number of devices referring to catalogue number]*
   - R – RESPIRATORY AND ANAESTHESIA DEVICES: *[free text – number of devices referring to catalogue number]*
   - S – STERILISATION DEVICES (EXCLUDING CAT. D – Z): *[free text – number of devices referring to catalogue number]*
   - T – PATIENT PROTECTIVE EQUIPMENT AND INCONTINENCE AIDS (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT – PPE): *[free text – number of devices referring to catalogue number]*
   - U – DEVICES FOR UROGENITAL SYSTEM: *[free text – number of devices referring to catalogue number]*
   - V – VARIOUS MEDICAL DEVICES: *[free text – number of devices referring to catalogue number]*
   - W – *IN VITRO* DIAGNOSTIC MEDICAL DEVICES: *[free text – number of devices referring to catalogue number]*
     - W01 – REAGENTS
       - CLINICAL CHEMISTRY *[free text – number of devices referring to catalogue number]*
       - IMMUNOCHEMISTRY (IMMUNOLOGY) *[free text – number of devices referring to catalogue number]*
       - HAEMATOLOGY / HAEMOSTASIS / IMMUNOHAEMATOLOGY / HISTOLOGY / CYTOLOGY *[free text – number of devices referring to catalogue number]*
       - MICROBIOLOGY (CULTURE) *[free text – number of devices referring to catalogue number]*
       - INFECTIOUS DISEASES *[free text – number of devices referring to catalogue number]*
       - GENETIC TESTING *[free text – number of devices referring to catalogue number]*
     - W02 – IVD INSTRUMENTS

        - CHEMISTRY / IMMUNOCHEMISTRY INSTRUMENTS *[free text – number of devices referring to catalogue number]*
        - HEMATOLOGY / HISTOLOGY / CYTOLOGY INSTRUMENTS *[free text – number of devices referring to catalogue number]*
        - MICROBIOLOGY INSTRUMENTS (CULTURES) *[free text – number of devices referring to catalogue number]*
        - INFECTIOUS IMMUNOLOGY INSTRUMENTS *[free text – number of devices referring to catalogue number]*
        - NUCLEIC ACID TESTING INSTRUMENTS *[free text – number of devices referring to catalogue number]*
        - SAMPLE PROCESSING SYSTEMS *[free text – number of devices referring to catalogue number]*
        - GENERAL PURPOSE IVD INSTRUMENTS *[free text – number of devices referring to catalogue number]*
        - IVD INSTRUMENTS – OTHER *[free text – number of devices referring to catalogue number]*
    - W03 – IVD GENERIC USE CONSUMABLES
        - SAMPLES COLLECTION DEVICES *[free text – number of devices referring to catalogue number]*
        - DEVICES FOR SAMPLES TRANSPORT (non-generic laboratory products) *[free text – number of devices referring to catalogue number]*
        - DEVICES FOR SAMPLES ANALYSES (no laboratory generic products) *[free text – number of devices referring to catalogue number]*
        - IVD GENERAL USE CONSUMABLE-DEVICES – OTHER ACCESSORIES *[free text – number of devices referring to catalogue number]*
        - IVD GENERAL USE CONSUMABLE DEVICES – OTHER *[free text – number of devices referring to catalogue number]*
- Y– DEVICES FOR PERSONS WITH DISABILITIES NOT INCLUDED IN OTHER CATEGORIES: *[free text – number of devices referring to catalogue number]*
- Z – MEDICAL EQUIPMENT AND RELATED ACCESSORIES, SOFTWARE AND CONSUMABLES: *[free text – number of devices referring to catalogue number]*

7. In which **role(s)** does your company operate*: *[multiple choice question; companies operating in both 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

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

MD

AIMDD/MDD

8. Please indicate the following according to your company portfolio*:

Note:
- **This refers to the catalogue numbers (not individual units of the catalogue number).
- *Purpose of these questions*: to get to know how many AIMDD/MDD devices and valid certificates your company has to date and how many you plan to transition to the MDR. It should give an indication of the expected availability of the company's medical devices on the market after transitioning to the MDR.

Devices

a. **Total number of AIMDD/MDD devices**** (in terms of the number of devices referring to the catalogue number) placed on the market **to date** [31/10/2023]: *[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 <u>for the first time</u> AND that you plan to transition to the MDR: *[free text – number of devices referring to catalogue numbers]*
- Of this total number, please specify the **percentage that you have already transferred to or you plan to transition to the MDR****: *[drop down]*
  - ≤10%
  - 11–20%
  - 21–30%
  - 31–40%
  - 41–50%
  - 51–60%
  - 61–70%
  - 71–80%
  - 81–90%
  - 91–100%
- If not all (100%) of the products have been transitioned or are planned to be transitioned to the MDR, what are the main reasons? *[Please choose max. 5 that apply]*
  - Not applicable since all products have been transferred.
  - The device is no longer state of the art and will be discontinued.
  - The device will be replaced with an updated/more innovative product.
  - The product is excluded from the scope of the MDR as per Article 1(6).
  - Product revenue does not justify the cost of transiting the device to the MDR.
  - The time to get certification takes too long.
  - Time to market is unpredictable.
  - Lack of clinical evidence.
  - Original equipment manufacturer/supplier stops production.
  - Disruptions in the supply chain. / Lack of raw materials and/or components. / Cost of raw material may be prohibitive.
  - Unavailability of a notified body.
    a. Please explain (e.g., if and how many NBs were contacted, waiting lists too long, no reply from NBs): *[please specify; free text, optional]*

- Other: *[please specify; free text]*

b. **Total number of devices** with valid AIMDD/MDD certificates** (in terms of the number of devices referring to the catalogue number) placed on the market **to date** (incl. Class Is/ Im, Class IIa, Class IIb, Class III) [31/10/2023]: *[free text – number of devices referring to catalogue numbers]*

Certificates

c. Total **number of valid AIMDD/MDD certificates to date [31/10/2023]**: *[free text – no. of valid certificates (QMS + product certificates)]*

- Of which total number of AIMDD/MDD certificates owned as an OBL manufacturer[4] to date [31/10/2023]: *[free text – no. of valid certificates]*

Notified body

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

9. Do you have **written agreements** with (a) notified body(ies) designated under the MDR?* *[select one option]*
   - Yes, all of the devices my company would like to transition to the MDR 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 MDR 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 MDR.
   - Not applicable – my devices do not need notified body involvement.

10. Did a notified body **refuse an application[5] under the MDR**? *
    - Yes
      - (optional) If yes, please indicate the 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]*

[4] Own Brand Labelling (OBL) means that a manufacturer of medical devices markets a CE marked device by an Original Equipment Manufacturer (OEM) under its own name. This practice is also known as a private label manufacturer or virtual manufacturer. [Source: NB KIWA]

[5] Application = Submission for certification

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

MDR implementation

- *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 work load for notified bodies.

Applications

11. How many **applications**** in total have you **lodged** under the MDR to your notified body(ies) [up to 31/10/2023]?*

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: If there are no applications or certificates for an annex, please write "0".

- Annex IX(I): *[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]*
- Of which no. of applications (all Annexes) covering new devices (devices which have never been CE-marked but will need CE-marking under the MDR to access the EU market – e.g. new devices, devices being up-classified, Annex XVI devices): *[free text – no. of applications]*

12. How many devices (catalogue number**) are undergoing the MDR conformity assessment process (accepted MDR applications still under review by NB) to date [31/10/2023]? 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/s/m: *[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]*

Written agreements

13. How many **written agreements**[6] **for certification under the MDR** with a notified body do you have **to date** [up to [31/10/2023]?* *[free text – no. of written agreements]*

Certificates

14. How many **certificates** have already been issued under the MDR by Annex for your portfolio **to date** [up to 31/10/2023]? If no certificates have been issued, please enter "0".*
    - Annex IX(I): *[free text – no. of certificates]*
    - Annex IX(II): *[free text – no. of 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]*
    - Annex XI(A): *[free text – no. of certificates]*
    - Annex XI(B): *[free text – no. of certificates]*

15. How many **devices** (catalogue number**) are covered by **certificates** that have already been issued under the MDR **to date**? 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]*
    - Class Ir/s/m: *[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]*
    - 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]*

Timelines [optional]

16. What is the **average time taken to prepare an application for MDR**[7] (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.

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

[6] Written agreements can be a framework agreement with NBs (covering several applications) or contracts for each application.

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

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

18. Comments on the time periods - MDR: [free text; optional]

Estimates

19. What is the **direct average cost per certificate**[8] in EURO that has already been issued under the MDR **to date [31/10/2023]**? Please enter "0" if not applicable or no answer can be provided.*
    - For QMS certificates:
      - total cost for initial certificate: *[free text - average cost for one certificate]*
      - yearly cost for maintenance: *[free text - yearly average cost for one certificate]*
    - For product certificates:
      - total cost for initial certificate: *[free text - average cost for one certificate]*
      - yearly cost for maintenance: *[free text - yearly average cost for one certificate]*

20. Of **your total portfolio** that requires an MDR certificate (and which you plan to transition to the MDR), 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%

21. For **how many devices** that are new** (new devices or those which have never been certified before - up-classified, Ir, class III custom-made devices) do you plan to submit an application to a NB in the next 12-18 months? * *[free text - number of devices referring to catalogue number]*

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

22. How many **MDR devices**** (MDD devices transitioned and new devices) do you (realistically) expect to have on the market **at the end of the applicable transitional period** (2027 or 2028)*: Please enter "0" if not applicable.

[8] Please calculate the direct costs for all certificates that have already been issued under the MDR for your portfolio to date - separately for "QMS only" and "product" certificates. Please calculate the average cost for one certificate. Only costs to be paid to notified bodies for audits and assessments leading to the initial certification [first line asked for] as well as follow-up costs for the notified body activities required by the Regulations to maintain the validity of certificates per year [second line asked for, i.e. fees for surveillance activities like annual audits, unannounced audits, evaluation of periodic safety update reports (PSUR), evaluation of summary of safety and clinical performance (SSCP)] should be provided. Internal cost as well as other external costs (e.g. costs of clinical investigations, consultant costs for helping with upgrading the QMS system and existing technical documentation to become MDR compliant or to prepare applications) should not be included. It is clear that these costs only show part of the picture and are not representative for the overall costs for MDR/IVDR certification.

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

- Class I: *[free text – number of devices referring to catalogue numbers 2027, number of devices referring to catalogue numbers 2028]*
- Class Ir: *[free text – number of devices referring to catalogue numbers 2027, number of devices referring to catalogue numbers 2028]*
- Class Is: *[free text – number of devices referring to catalogue numbers 2027, number of devices referring to catalogue numbers 2028]*
- Class Im: *[free text – number of devices referring to catalogue numbers 2027, number of devices referring to catalogue numbers 2028]*
- Class IIa: *[free text – number of devices referring to catalogue numbers 2027, number of devices referring to catalogue numbers 2028]*
- Class IIb: *[free text – number of devices referring to catalogue numbers 2027, number of devices referring to catalogue numbers 2028]*
- Class III: *[free text – number of devices referring to catalogue numbers 2027, number of devices referring to catalogue numbers 2028]*

23. How many **MDR certificates per annex** do you (realistically) expect to have **at the end of the applicable transitional period** (2027 or 2028)*: Please enter "0" if not applicable.
    - Annex IX(I): *[free text – no. of certificates 2027, no. of certificates 2028]*
    - Annex IX(II): *[free text – no. of certificates 2027, no. of certificates 2028]*
    - Annex X: *[free text – no. of certificates 2027, no. of certificates 2028]*
    - Annex XI(A): *[free text – no. of certificates 2027, no. of certificates 2028]*
    - Annex XI(B): *[free text – no. of certificates 2027, no. of certificates 2028]*

24. Do you plan to transition **products without an intended medical purpose listed in Annex XVI** to the MDR?

Note:
Products without an intended medical purpose that are listed in Annex XVI to the MDR are covered by that Regulation from 22 June 2023, which is the date of application of Annex XVI common specifications set out in Commission Implementing Regulation (EU) 2022/2346.

- No
- Yes
    - If yes, how many types of products do you plan to transition to the MDR for each of the groups listed in Annex XVI (if no products will be transitioned please indicate "0")?
        - Group 1: *[free text – no. of types]*
        - Group 2: *[free text – no. of types]*
        - Group 3: *[free text – no. of types]*
        - Group 4: *[free text – no. of types]*
        - Group 5: *[free text – no. of types]*
        - Group 6: *[free text – no. of types]*

25. Do you plan to transition **dual purpose devices** (products having both a medical and a non-medical intended purpose) to the MDR?
    - No
    - Yes
        - If yes, how many types of dual purpose devices do you plan to transition to the MDR for each of the groups listed in Annex XVI (if no products will be transitioned please indicate "0")?
            - Group 1: *[free text – no. of types]*

- Group 2: *[free text – no. of types]*
- Group 3: *[free text – no. of types]*
- Group 4: *[free text – no. of types]*
- Group 5: *[free text – no. of types]*
- Group 6: *[free text – no. of types]*

Discontinued medical devices

26. 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 codes if applicable]*
        - If yes, what were the main reasons for product discontinuation? *[please select the main 5 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[9] 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

27. Do you **plan to discontinue some products on the EU market in the coming months**? *
    - Yes
        - If yes, which kind of medical devices will be affected? *[free text – please indicate the relevant EMDN codes if applicable]*
        - If yes, what are the main reasons for product discontinuation? *[please select the main 5 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

[9] 'Orphan device' means a medical device specifically intended to benefit patients in the treatment or diagnosis [or prevention] of a disease or condition that has an annual incidence* of not more than 1 in 37,000 per year in the EU. [* To be calculated on the basis of an EU-population of 447 Mio; ~12.000 cases per year]. This is a working definition for the purpose of this study, which may however further develop.

        - Disruptions in the supply chain / Supplier stops production
        - Other: *[please specify]*
    - If yes, will orphan/niche devices[10] or orphan indications be affected?
        - Yes
        - No
    - If yes, will Own Brand Labelled devices be affected?
        - Yes
        - No
- No

Preparedness of manufacturers

28. Do you have an MDR compliant QMS?* *[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 MDR compliant QMS today but it has not yet been certified.
    - No, we do not yet claim to operate an MDR compliant QMS but we are confident that we will meet the deadline of 26 May 2024.
    - No, we have concerns about meeting the deadline of 26 May 2024 to operate an MDR compliant QMS.
    - Not applicable

29. Have you already transferred your products/technical documentation to the MDR?* *[please tick one option]*
    - Yes, our first product(s) has(have) been MDR certified.
    - Yes, we have submitted products for MDR certification and are progressing towards certification.
    - Yes, we have submitted products but have insufficient feedback from NBs to be confident that we will obtain MDR certification in time.
    - No, we have not yet submitted but are confident that we will meet the application deadline of 26 May 2024 for timely certification thereafter.
    - No, we have concerns about meeting the application deadline of 26 May 2024.
    - Not applicable

[10] 'Orphan device' means a medical device specifically intended to benefit patients in the treatment or diagnosis [or prevention] of a disease or condition that has an annual incidence* of not more than 1 in 37,000 per year in the EU. [* To be calculated on the basis of an EU-population of 447 Mio; ~12.000 cases per year]. This is a working definition for the purpose of this study, which may however further develop.

2.3 IVD: Questionnaire on IVDs

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

IVD

IVDD

- *Purpose of these questions*: to monitor the progress of the transition status of devices to the IVDR.

30. Please indicate the following according to your **company portfolio**:*

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

Devices

a. **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) [31/10/2023]: *[free text - number of IVDs referring to catalogue numbers]*

i. Of this total number, please specify the number of IVDs** which are self-tests: *[free text - number of IVDs referring to catalogue numbers]*

ii. Of this total number, please specify the **percentage that you have already transferred to or plan to transition to the IVDR****: *[drop down]*

- ≤10%
- 11-20%
- 21-30%
- 31-40%
- 41-50%
- 51-60%
- 61-70%
- 71-80%
- 81-90%
- 91-100%

iii. If not all (100%) of the products have been transitioned or are planned to be transitioned to the IVDR, what are the main reasons? *[Please choose max. 5 that apply]*

- Not applicable since all products have been transferred.
- The device is no longer state of the art and will be discontinued.
- The device will be replaced with an updated/more innovative product.
- The product is excluded from the scope of the IVDR as per Article 1(3).
- Product revenue does not justify the cost of transiting the device to the IVDR.
- The time to get certification takes too long.
- Time to market is unpredictable.
- Lack of clinical evidence.
- Original equipment manufacturer/ supplier stops production.
- Disruptions in the supply chain. / Lack of raw materials and/or components. / Cost of raw material may be prohibitive.
- Unavailability of a notified body

a. Please explain (e.g., if and how many NBs were contacted, waiting lists too long, no reply from NBs): *[please specify; free text]*
   - Other: [please specify; free text]

b. Of this total number, please specify the number of **IVDD devices**** that will need NB intervention <u>for the first time</u> AND you plan to transition to the IVDR: *[free text – number of IVDs referring to catalogue numbers]*

c. **Total number of devices** with valid IVDD certificates** (in terms of the number of devices referring to the catalogue number) placed on the market **to date** (incl. IVDs for self-testing (Annex III.6), IVDs in Annex II – List A & B) [31/10/2023]: *[free text – number of devices referring to catalogue numbers]*

Certificates

d. Total **number of valid IVDD certificates to date** [31/10/2023]: *[free text – no. of valid certificates (QMS + product certificates)]*

   i. Of which total number of IVDD certificates owned as an OBL manufacturer[11] to date [31/10/2023]: *[free text – no. of valid certificates]*

Notified body

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

31. Do you have **written agreements** with (a) notified body(ies) designated under the IVDR?*
    - Yes, <u>all of the devices</u> my company would like to transition to the IVDR <u>are covered by written agreements</u> with one or several notified body(ies).
    - Yes, but <u>only some of the devices</u> 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.

32. Did a notified body **refuse an application[12] under the IVDR**?*
    - Yes
      - (optional) If yes, please indicate the time passed since application was sent until refusal *[drop down]*
        - Less than 6 months

[11] Own Brand Labelling (OBL) means that a manufacturer of medical devices markets a CE marked device by an Original Equipment Manufacturer (OEM) under its own name. This practice is also known as a private label manufacturer or virtual manufacturer. [Source: NB KIWA]

[12] Application = Submission for certification

        - 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]*
- 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 work load for notified bodies.

Applications

33. How many **applications** in total have you **lodged under the IVDR to your notified body(ies)** [up to 31/10/2023]?*

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: If there are no applications or certificates for an annex, please write "0".

- Annex IX(I): *[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(A): *[free text – no. of applications; of which no. of applications lodged for changes]]*
- Of which Class D devices (all Annexes): *[free text – no. of applications]*
- Of which requiring consultation for companion diagnostics (all Annexes): *[free text – no. of applications]*

34. How many devices (catalogue number**) are undergoing the IVDR conformity assessment process (accepted IVDR applications still under review by NB) to date [31/10/2023]? 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]*

Written agreements

35. How many **written agreements for certification under the IVDR**[13] with a NB do you have **to date** [up to 31/10/2023]?* *[free text – no. of written agreements]*

[13] Written agreements can be a framework agreement with NBs (covering several applications) or contracts for each application.

Certificates

36. How many **certificates** have already been issued under the IVDR by Annex for your portfolio **to date** [up to 31/10/2023]? If no certificates have been issued, please enter "0".*
    - Annex IX(I): *[free text – no. of certificates]*
    - Annex IX(II): *[free text – no. of certificates]*
    - Annex X: *[free text – no. of certificates]*
    - Annex XI(A): *[free text – no. of certificates]*

37. How many **devices** (catalogue number**) are covered by **certificates** that have already been issued under the IVDR **to date** [up to 31/10/2023]? 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]*

Timelines [optional]

38. 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.
39. What is the **time taken to reach issuance of a new EC certificate** (from written agreement signed to issuance) under the IVDR? *[drop down]*
    - 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.
40. Comments on the time periods – IVDR: *[free text; optional]*

Estimates

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

41. What is the **direct average cost per certificate**[15] in Euro that has already been issued under the IVDR **to date**? If no certificates have been issued or no answer can be provided, please enter "0".*

- For QMS certificates:
  a. total cost for initial certificate: *[free text –average cost for one certificate]*
  b. yearly cost for maintenance: *[free text – yearly average cost for one certificate]*
- For product certificates:
  c. total cost for initial certificate: *[free text –average cost for one certificate]*
  d. yearly cost for maintenance: *[free text – yearly average cost for one certificate]*

42. Of **your total portfolio** that requires an IVDR certificate (and which you plan to transition to the IVDR), what percentage **has already received an IVDR certificate**? * *[drop down]*

- ≤10%
- 11–20%
- 21–30%
- 31–40%
- 41–50%
- 51–60%
- 61–70%
- 71–80%
- 81–90%
- 91–100%

43. For **how many devices** that are new** (new devices or those which have never been certified before) do you plan to submit an application to a NB in the next 12–18 months? *[free text – number of IVDs referring to catalogue numbers]*

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

44. How many **IVDR devices**** do you (realistically) expect to have on the market **at the end of the applicable transitional period** (2025, 2026 or 2027): *

- Total: *[free text – number of IVDs referring to catalogue numbers 2025, number of IVDs referring to catalogue numbers 2026, number of IVDs referring to catalogue numbers 2027]*
- Class A: *[free text – number of IVDs referring to catalogue numbers 2025, number of IVDs referring to catalogue numbers 2026, number of IVDs referring to catalogue numbers 2027]*
- Class B: *[free text – number of IVDs referring to catalogue numbers 2025, number of IVDs referring to catalogue numbers 2026, number of IVDs referring to catalogue numbers 2027]*
- Class C: *[free text – number of IVDs referring to catalogue numbers 2025, number of IVDs referring to catalogue numbers 2026, number of IVDs referring to catalogue numbers 2027]*

[15] Please calculate the direct costs for all certificates that have already been issued under the IVDR for your portfolio to date – separately for "QMS only" and "product" certificates. Only costs to be paid to notified bodies for audits and assessments leading to the initial certification [first line asked for] as well as follow-up costs for the notified body activities required by the Regulations to maintain the validity of certificates per year [second line asked for, i.e. fees for surveillance activities like annual audits, unannounced audits, evaluation of periodic safety update reports (PSUR), evaluation of summary of safety and clinical performance (SSCP)] should be provided. Internal cost as well as other external costs (e.g. costs of clinical investigations, consultant costs for helping with upgrading the QMS system and existing technical documentation to become IVDR compliant or to prepare applications) should not be included. It is clear that these costs only show part of the picture and are not representative for the overall costs for MDR/IVDR certification.

- Class D: *[free text – number of IVDs referring to catalogue numbers 2025, number of IVDs referring to catalogue numbers 2026, number of IVDs referring to catalogue numbers 2027]*

45. How many **IVDR certificates per annex** do you (realistically) expect to have **at the end of the applicable transitional periods** (2025, 2026 or 2027): *
    - Annex IX(I): *[free text – no. of certificates 2025, no. of certificates 2026, no. of certificates 2027]*
    - Annex IX(II): *[free text – no. of certificates 2025, no. of certificates 2026, no. of certificates 2027]*
    - Annex X: *[free text – no. of certificates 2025, no. of certificates 2026, no. of certificates 2027]*
    - Annex XI(A): *[free text – no. of certificates 2025, no. of certificates 2026, no. of certificates 2027]*

Discontinued IVDs

46. Have you **stopped the production/marketing/supply of some IVDs to the EU market since 2021?** *
    - Yes
        - If yes, which kind of IVDs were affected? *[free text – please indicate the relevant EMDN codes if applicable]*
        - If yes, what were the main reasons for product discontinuation? *[please select the main 5 that apply]*
            - Manufacturer recalls or safety concerns
            - Decisions/recommendations by national competent authorities
            - Products at the end of their life cycle
            - Products with sales volumes
            - Products with 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

47. Do you **plan to discontinue some IVDs on the EU market in the coming months**? *
    - Yes
        - If yes, which kind of IVDs were affected? *[free text – please indicate the relevant EMDN codes if applicable]*

[16] 'Orphan device' means a medical device specifically intended to benefit patients in the treatment or diagnosis [or prevention] of a disease or condition that has an annual incidence* of not more than 1 in 37,000 per year in the EU. [* To be calculated on the basis of an EU-population of 447 Mio; ~12.000 cases per year]. This is a working definition for the purpose of this study, which may however further develop.

- If yes, what are the main reasons for product discontinuation? *[please select the main 5 that apply]*
  - Manufacturer recalls or safety concerns
  - Decisions/recommendations by national competent authorities
  - Products at the end of their life cycle
  - Products with sales volumes
  - Products with 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

48. Do you have an **IVDR compliant QMS**? * *[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 we are confident that we will meet the deadline of 26 May 2024.
    - No, we have concerns about meeting the deadline of 26 May 2024 to operate an IVDR compliant QMS.
    - Not applicable

49. 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 meet the application deadline of 26 May 2024 for timely certification thereafter.
    - No, we have concerns about meeting the application deadline of 26 May 2024.
    - Not applicable

[17] 'Orphan device' means a medical device specifically intended to benefit patients in the treatment or diagnosis [or prevention] of a disease or condition that has an annual incidence* of not more than 1 in 37,000 per year in the EU. [* To be calculated on the basis of an EU-population of 447 Mio; ~12.000 cases per year]. This is a working definition for the purpose of this study, which may however further develop.

2.4 AR-MD/IVD: Questionnaire for authorised representatives

AR

50. 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)

51. 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

52. 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.

53. Have any of your clients cancelled the agreement with you as an authorised representative for some MDs/IVDs since 2021?*
    - Yes
        - If yes, please provide the percentage of clients who have terminated the agreement. *[optional, percentage]*
        - If yes, what were the main reasons for cancelling the agreement? *[optional, multiple choice]*
            - Client stopped the production/marketing/supply of MDs/IVDs
                - worldwide
                - to the EU market
            - Change of authorised representative
            - Other: *[please specify]*
    - No
    - I don't know / not applicable.

2.5 Closing

Any other issue

54. Is there **anything else** that you would like to share with us? Do you have any concerns or suggestions? *[free text]*
55. 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.