Webinar for economic operators

(manufacturers, authorized representatives, importers, distributors)

Study supporting the monitoring of availability of medical devices on the EU market **(HaDEA/2021/P3/03)**

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Austrian National Public Health Institute /
Gesundheit Österreich GmbH (GÖG)

16 January 2025, 11.00-12.00, online

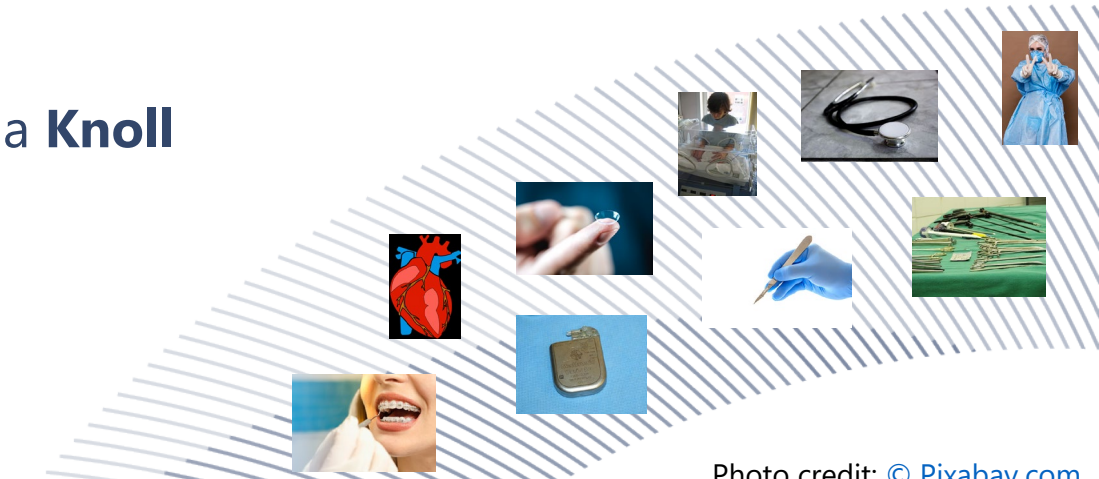


Photo credit: © Pixabay.com

Rules of participation

- Please **mute** your microphone when you are not speaking. 
- Please use the "**raise your hand function**" if you have questions. 

- Please also use the **chat function** for additional information or if you have a question. The facilitator will either read the question afterwards or give you the floor for stating your question (turn microphone on).
- Please be informed that this **webinar** will be **recorded**.

Available at our website after the webinar:
https://ppri.goeg.at/Study_MD_Availability

Content

1. About the „Study supporting the monitoring of availability of medical devices on the EU market“
2. Second survey with economic operators
3. EUSurvey tool
4. Q&A

1. About the ‘Study supporting the monitoring of availability of medical devices on the EU market’

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

Commissioned by:
The European Commission's Directorate-General for Health and Food Safety (DG SANTE)
via the European Health and Digital Executive Agency (HaDEA) - **HADEA/2021/P3/03**

Aim: To support monitoring and analyzing the availability of medical devices and in vitro diagnostic medical devices on the EU market in the context of the implementation of medical devices and in vitro diagnostic medical devices Regulations **from the perspectives of key stakeholders**

Geographic scope: 31 countries (27 EU Member States plus Iceland, Liechtenstein, Norway and Turkey)

Duration:
2 December 2022 – 1 December 2025 (36 months)

Study team:

- **Project lead:** Gesundheit Österreich GmbH (GÖG) / Austrian National Public Health Institute → project lead
- **Project partners:** Areté, Civic Consulting
- **Supported by an Expert Advisory Group:** Four MD experts providing methodological and thematic support

Contact: Ms Friederike Windisch (project manager), Ms Nina Zimmermann (deputy project manager) → medical.devices@goeg.at

Overview of ongoing and planned survey activities

Key stakeholder groups	Overview and status of the survey activities
1. Notified bodies	*Completed* • **NB surveys #1-11:** results published (dashboard) *Ongoing* • **NB survey #12** (small, medium and large dataset, questions for the targeted evaluation): survey completed and data validation ongoing *Planned* • **NB survey #13** (small dataset; questions for the targeted evaluation): survey launch planned on 20/01/2025 • **NB survey #14** (small and medium dataset): planned survey launch on 03/03/2025 • **NB survey #15** (small dataset): planned survey launch on 05/05/2025 • **NB survey #16** (small, medium and large dataset): planned survey launch on 01/07/2025 • **NB survey #17** (small dataset): planned survey launch on 01/09/2025

2. Economic operators	*Completed*
	• **EO survey #1** (MF/AR): completed and results published (dashboard + PPT)
	Ongoing
	• **EO survey #2** (MF/AR/IM/DB): based on 1st MF/AR survey and questions for the targeted evaluation
	  • Target groups: manufacturers, authorized representatives, importers, distributors
	  • Survey launch on 19/12/2024
	  • Survey link: https://ec.europa.eu/eusurvey/runner/2024MDAvailabilityMFARIMDBsurvey#
	  • Deadline: 28 February 2025

3. Health service providers, medical societies, medical doctors	*Completed* • **HSP survey:** final results will be published in dashboard version 3.0 in Q1/2025
4. Patient representatives	• preparation phase
5. Competent authorities	• preparation phase

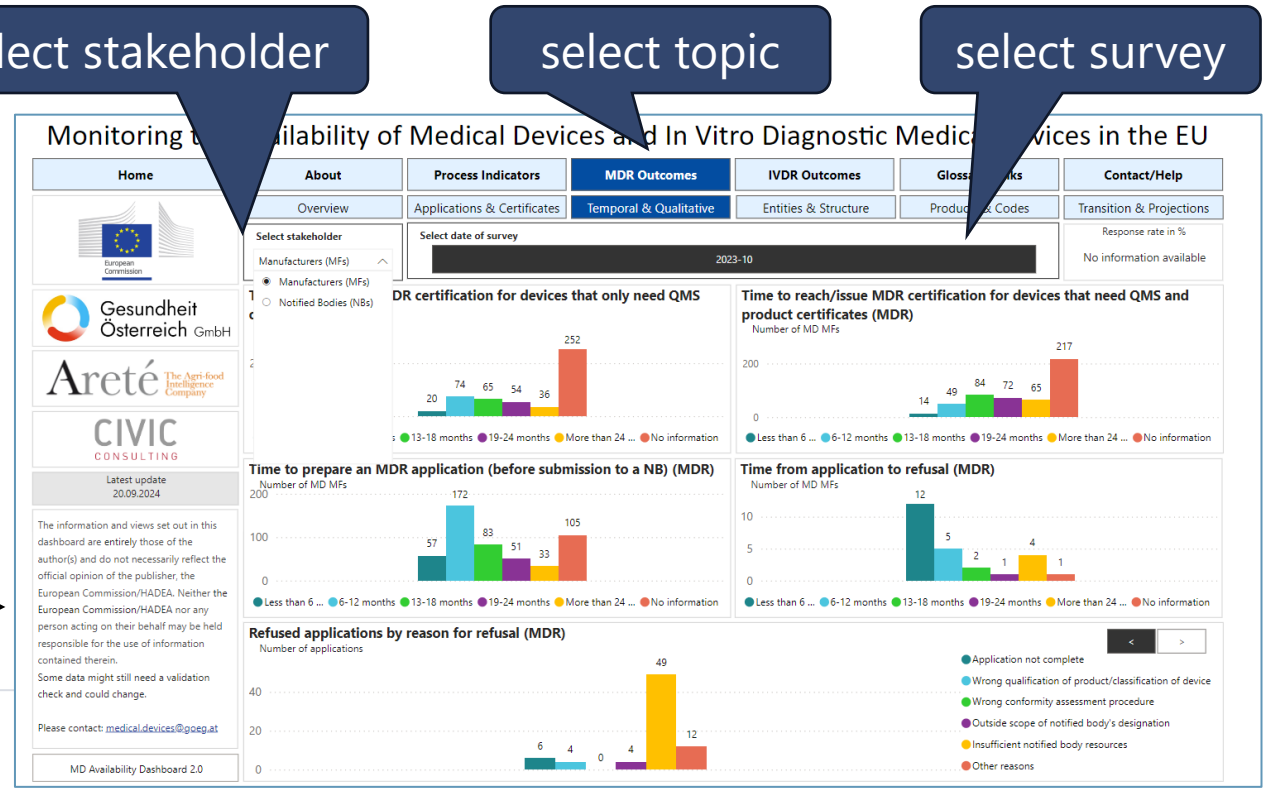
Thank you for your support in this study!

Please support us in promoting the survey! LinkedIn post

Publication of survey results in the dashboard

- **Study results** are presented in aggregated form in a **publicly available** and **regularly updated** dashboard (MS Power BI)
- **Dashboard content** *(version 2.2; last update on 28/11/2024):*
  - Results of eleven notified body surveys:
    March 2023, April 2023, May 2023, June 2023, August 2023, October 2023, December 2023, February 2024, April 2024, June 2024, August 2024
  - Results of one survey with manufacturers and authorized representatives: October 2023
  - Data available from previous surveys starting in 2021 (conducted by the European Commission)

LINK to the study and dashboard



2. Second survey with economic operators

About the survey

- **Survey tool**: EU survey
- **Survey link:** https://ec.europa.eu/eusurvey/runner/2024MDAvailabilityMFARIMDBsurvey#
- **Survey period:**
  - **Survey launch:** 19 December 2024
  - **Survey deadline**: 28 February 2025 (23:59 CET)
  - Survey covers data up to 31/10/2024
- **Target group:**
  manufacturers, authorized representatives, importers and distributors of MDs and IVDs
- **Development of the survey:**
  The survey builds upon previous surveys conducted in this field and the 1st survey with manufacturers and authorized representatives.
  It was developed together with DG SANTE and the MDCG TF on certification capacity monitoring and industry representatives. Some questions are the same as in the survey for NBs. NBs
- **Targeted evaluation**:
  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. TE

Data confidentiality

Full anonymity guaranteed!

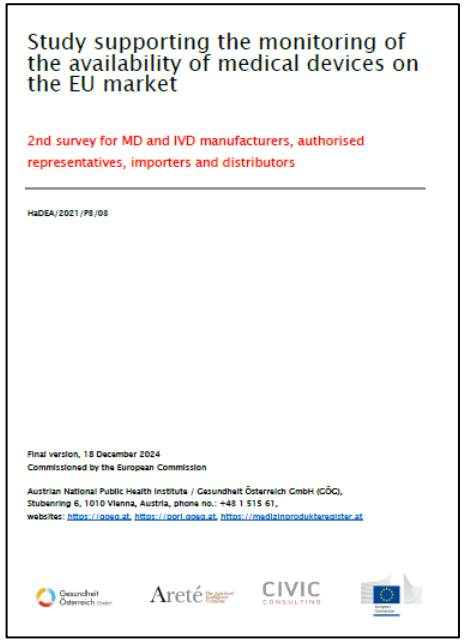
- Acting in **full compliance with GDPR** and EU competition law
- **Pseudonymisation of raw data**
- **Contact information**
  - only used to delete potential double submissions from the same company/subsidiaries
  - deleted as soon as no longer needed to process the results
- **Company-level data**: neither shared with 3rd parties nor disclosed
- **Only aggregated outcomes published**

Structure

About you and your company

Part MF-MD applicable for MFs of MD

Part MF-IVD applicable for MFs of IVD


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/PS/08

Final version, 18 December 2024
Commissioned by the European Commission

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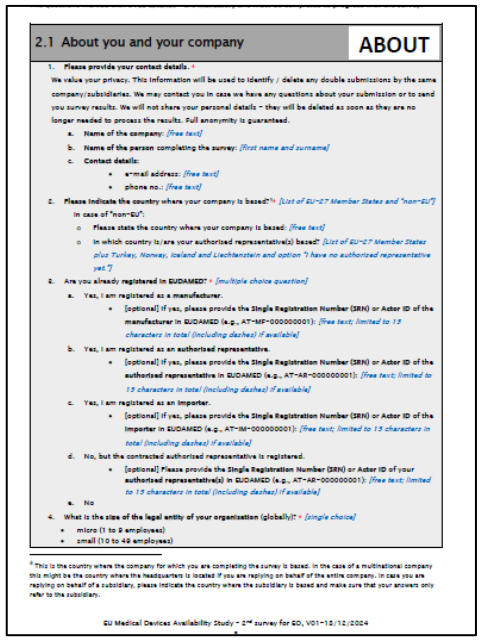
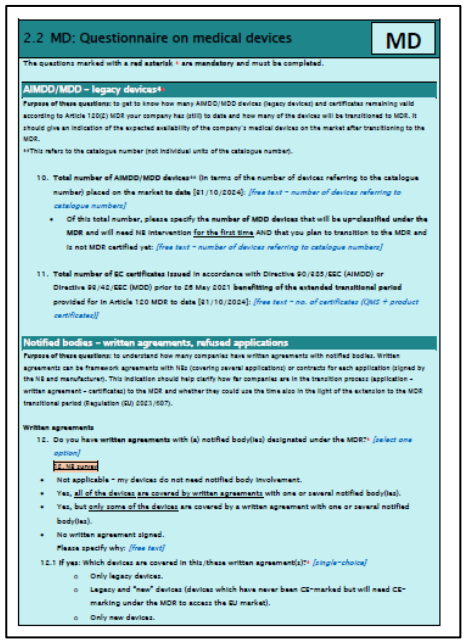
Stubenring 6, 1010 Vienna, Austria, phone no.: +48 1 515 61,
websites: https://goeg.at, https://epi.goeg.at, https://medizinprodukteregister.at


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?* [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 13 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 13 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 13 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 13 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)

* 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.

EU Medical Devices Availability Study – 2nd survey for GD, V01-10/12/2024


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*

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)]

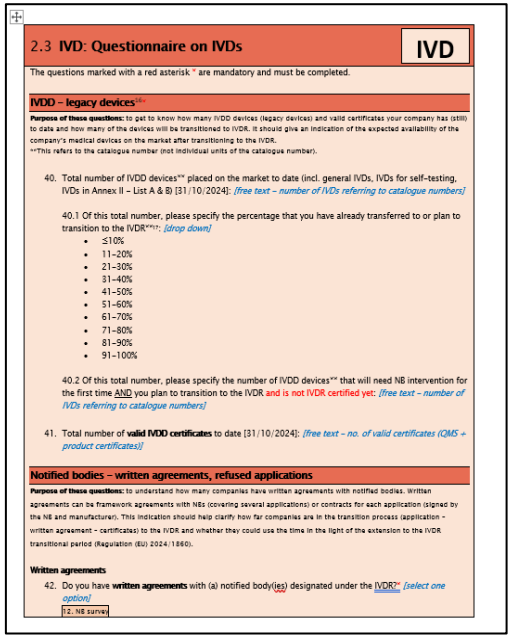
Notified bodies – written agreements, refused applications

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.


2.3 IVD: Questionnaire on IVDs IVD

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

IVDD – legacy devices*

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***: [drop down]
- ≤10%
- 11–20%
- 21–30%
- 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)]

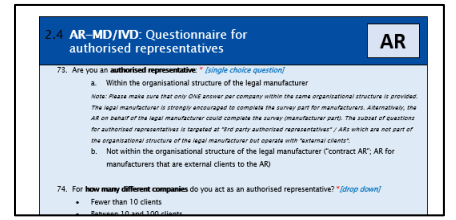
Notified bodies – written agreements, refused applications

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

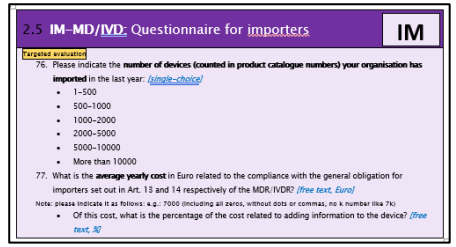
For ARs of MD/IVD


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 for authorised representatives is targeted at "first 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

For importers of MD/IVD

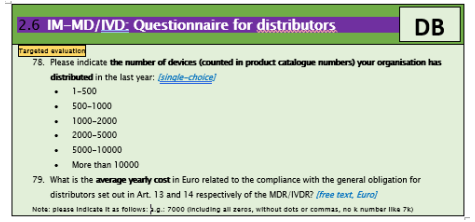

2.5 IM–MD/IVD: Questionnaire for importers IM

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, %]

For distributors of MD/IVD


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)

Part 1) About you and your company:

1) Contact details
2) Country where company is based
3) Registration in EUDAMED
4) Size of the company (SME, etc.)
5) Staff employed for regulatory compliance TE
6) Start-up?
7) Where products are available
8) Which device areas included in the product portfolio
9) In which roles does your company operate? (trigger question for survey parts)
   - 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)
   - Importer (IM)
   - Distributor (DB)

Please only provide one answer per company!

Survey part for manufacturers of MD

AIMDD/MDD – legacy devices

10) Total no. of AIMDD/MDD devices

11) Total number of EC certificates (AIMDD/MDD) benefitting of the extended transitional period provided for in Article 120

Notified bodies – written agreements, refused applications

12) Written agreements with NBs

13) Refused applications

MDR implementation – applications, certificates, time periods

14) How many applications lodged (by Annex)

15) How many devices undergoing MDR conformity assessment process

16) MDR certificates received (yes/no) (trigger question for other survey parts – recertification/costs)

17) How many MDR certificates received (by Annex)

18) How many devices covered in MDR certificates (total, new devices (novel or breakthrough), by risk class)

If not applicable, please enter „0“!

Survey part for manufacturers of MD

Recertification (only if 16 = yes)

19-23) questions on recertifications (how many certificates expire, if a certificate was renewed, time periods)

Time periods

24) For the preparation of an application

25) Average timeframe between application and witten agreement

26) Average time to reach issuance of a new certificate (from written agreement signed)

27) Time with MF/NB

28) Comments

Costs (only if 16 = yes) TE

29) Total cost for drawing up the clinical evaluation by risk class

30) Costs for certificates per MDR Annex (costs for the first and last certificate received plus several subquestions on the details of the certificate (how many devices, if consultants were involved, how much fees paid to NBs, cost categories)

31) Costs of recertification (costs of the last renewed certificate (product or QMS) and subquestions)

Survey part for manufacturers of MD

Estimates

32) Percentage of product portfolio that has already received an MDR certificate

Discontinued MD

33) Stopped production since 2021?

Preparedness of MF

34) Impact of the revised transitional periods

Other questions for the targeted evaluation TE

35) Clinical investigation reports

36) Publicly available?

37) Summaries of clinical safety and performance

38) Publicly available?

39) No. of field safety corrective actions

Similar questions for MF of IVDs

Other survey parts

For AR

73) AR organisational structure

74) How many companies

75) Transition to MDR / IVDR

For importers / For distributors

TE

76) Number of devices imported / distributed

77) Costs related to compliance with general obligation Art. 13 and 14 MDR/IVDR

2nd EO survey – supporting tools

- Brief glossary: https://ppri.goeg.at/system/files/inline-files/MD_Availability_Glossary_HaDEA_2021_P3_03_April_2023.pdf

Availability of MD/IVD on the EU market in the context of the implementation of MDR and IVDR

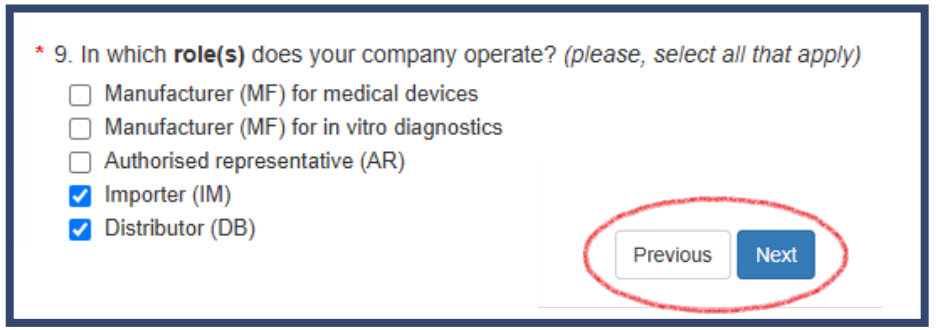
- Instructions for Use (for the dashboard)

- Webinar recorded
  (will be made available at our website: https://ppri.goeg.at/Study_MD_Availability)

3. EUSurvey tool

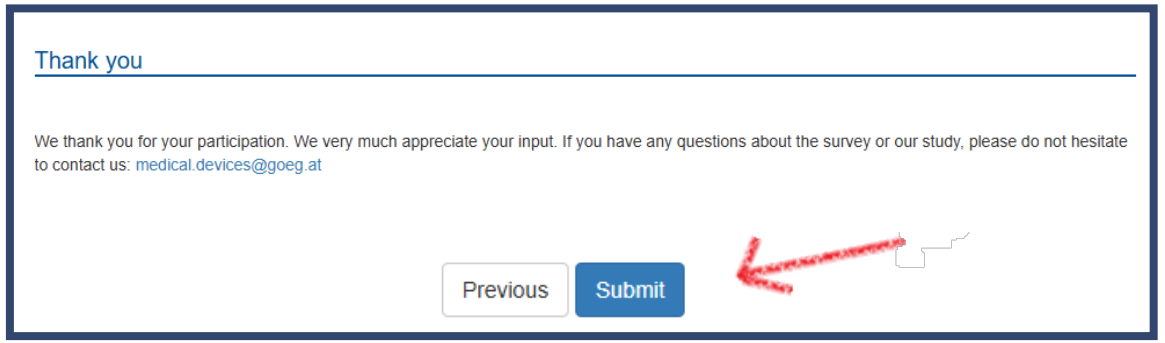
Key instructions

- Navigate through the questionnaire using the "previous" and "next" buttons at the end of each page
- To change a reply, it is sufficient to go back to the question and modify it.



- Fields marked with (*) are **mandatory**. In case of missing mandatory replies, an error message ("This field is required") in red is displayed on top of the question when the respondent moves forward in the questionnaire.
- Additional instructions will appear in case of errors in the answer (e.g.: "*This is not a valid e-mail address*").

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



Important tips

- You can download the **full questionnaire** anytime by clicking on the button "Survey questionnaire PDF".
- You can save a **draft of the survey in progress** via the **dedicated button on the right end of each page**. This generates a **personalised link** with your survey draft to come back to it.

  → Tip: We advise to often save the progress made. Re-loading the page after a time-out will not recover previous answers.

Please pay **specific attention** to:

- Indicate your **contact details** at Question 1
- Indicate if you are registered in **EUDAMED** at question 3
- The correct **role of your company** at Question 9 → on the basis of this reply, the correct set of questions that are relevant for your company will be displayed

The study team remains available in case of questions at the following e-mail addresses:

medical.devices@goeg.at
questions on the study and survey design/topics

policyevaluation@areteagrifood.com
technical questions on the online survey tool and related issues

4. Q&A

Thank you for participating in the survey!

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

Deadline: 28 February 2025 (23:59 CET)

Contact: medical.devices@goeg.at

Source: Pixabay.com

Gesundheit Österreich GmbH