
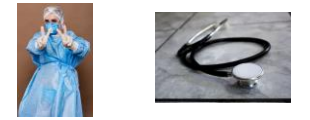






WEBINAR for manufacturers and AR of MD and IVDs

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

7 December 2023, 1-2pm CET

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Online via Zoom

Areté The Agri-food Intelligence Company

CIVIC CONSULTING

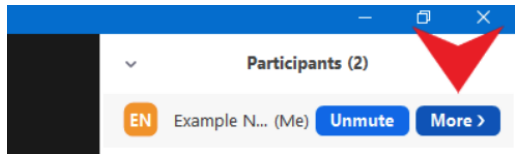
Gesundheit Österreich GmbH

Agenda

1. Welcome and brief introduction to the study
2. Presentation of the survey
3. EUSurvey tool
4. Questions and answers

Rules of participation

- Please mute your microphone when you are not speaking.
- Please use the "raise your hand function" if you have questions. Raise Hand
- 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 state your name and NBs name and/or country first.
- Please be informed that this webinar will be recorded.
- Please state your name in the participants list: To change your name after entering a Zoom meeting, click on the "Participants" button at the top of the Zoom window. Next, hover your mouse over your name in the "Participants" list on the right side of the Zoom window. Click on "More" and "Rename".



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1. Brief introduction to the “Study supporting the monitoring of availability of medical devices on the EU market”

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Key facts

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**

Consortium:

- **Project lead:** Gesundheit Österreich GmbH (GÖG) / Austrian National Public Health Institute
- **Project partners:** Areté, Civic Consulting

Project manager:

Ms Friederike Windisch, Ms Nina Zimmermann (deputy)

Key contacts HaDEA/DG SANTE:

Ms Erica Poot (HaDEA), Ms Maria-Chiara Orlandi (DG SANTE)

Duration:

2 December 2022 – 1 December 2025 (36 months)

Study objectives

General objective:

To **monitor and analyse the availability of 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**

Five specific objectives (SO):

- SO1: To **map all relevant stakeholders** which play a crucial role in ensuring the availability of medical devices on the European market (Stakeholder mapping - to make sure we ask the right players)
- SO2: To **identify the relevant data and information** needed and to identify appropriate data sources (Identification of quantitative and qualitative data needs – to make sure we collect the relevant data)
- SO3: To **design a dashboard**, including relevant indicators, and draft reports that describe the outcomes of the data collection in a user-friendly layout (Data compilation and presentation)
- SO4: To analyse per stakeholder group the **barriers** and **opportunities**. The analyses will look into the underlying cause, the phase in the life-cycle of the product (before / during certification) and the risk class/type of devices in the light of current developments at the time of the surveys (Analysis)
- SO5: To **develop a set of fit-for-purpose solutions** to address barriers and opportunities related to availability of MD at regular intervals, with reference to the new EU Regulations and their developments and in close cooperation with HaDEA/DG SANTE, EAG and the MDCG taskforce (Recommendations).

Key stakeholders

Close cooperation

MDCG

1. Notified Bodies

Work largely impacts whether or not MD and IVD will become available on the market

Produce MD and/or IVD and guide the own conformity assessment process or involve a Notified Body (if required)

2. Economic operators

4. Patient represen-tatives

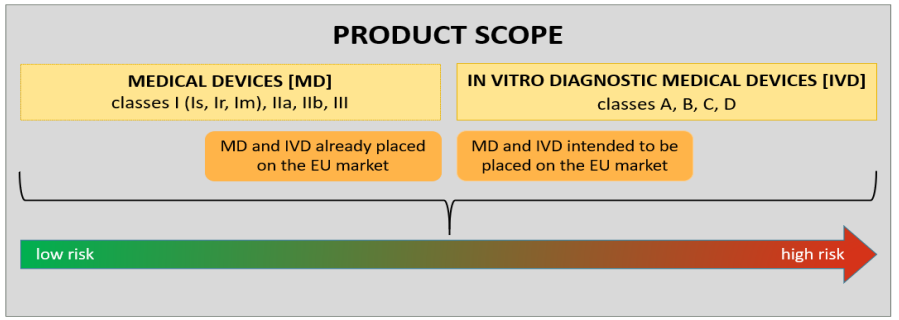
Allows identification of potential problems and weaknesses from the patient perspectives

Up to them that numerous MD and IVD are actually used; ensure access of the products to patients in practice

3. Health service providers

Medical societies, medical doctors

Scope of the study



Product scope:

- **Product types:** medical devices (MD) and in vitro diagnostic medical devices (IVD)
- **Market status:** devices placed on the market (available under the new regulations) and those intended to be placed on the market in future (not yet available under the new regulations) and also taking into account legacy and new devices
- **Risk classes:** devices belonging to all risk classes, but with a focus on devices requiring the involvement of NB
- **Focus** will be set on special product groups (e.g. orphan and/or niche devices) and those at risk of shortage

Geographic scope: 30 countries (27 EU countries plus Iceland, Liechtenstein and Norway as new regulations cover the EEA)

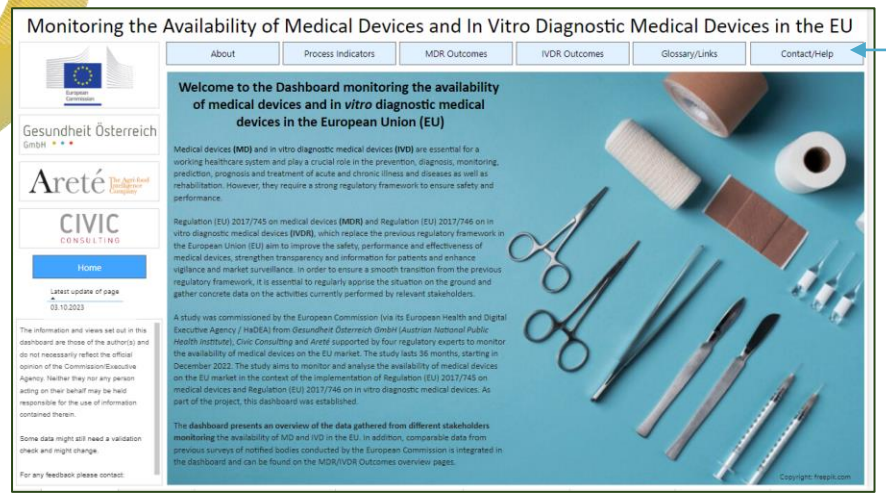
Overview of the tasks

Task 0: Project management and communication	Task 1: Study design	Task 2: Consultation activities	Task 3: Analysis

• **0.1** Understanding of the assignment
• **0.2** Development of the assignment
• **0.3** Progress communication
	• **1.1** Preliminary desk and field research
	• **1.2** Methodological approach
	• **1.3** Consultation strategy
	• **1.4** Development of a dashboard
	• **1.5** Performance indicators
		• **2.1** Targeted consultations: interviews and surveys
		• **2.2** Targeted consultations: MDCG taskforce meetings
			• Analysis of
			  • literature
			  • interviews
			  • surveys
			  • non-sensitive information from MDCG task force meetings and project internal meetings

Public Dashboard (MS Power BI)

Results are presented in aggregated form in a **publicly available** and **regularly updated** dashboard
including relevant indicators, consisting by tables, graphs and other tools useful to show the results of the collected data

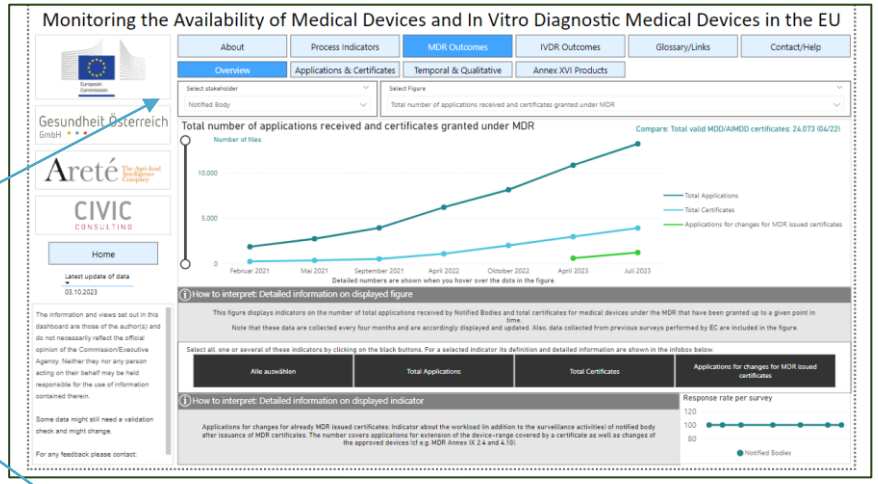


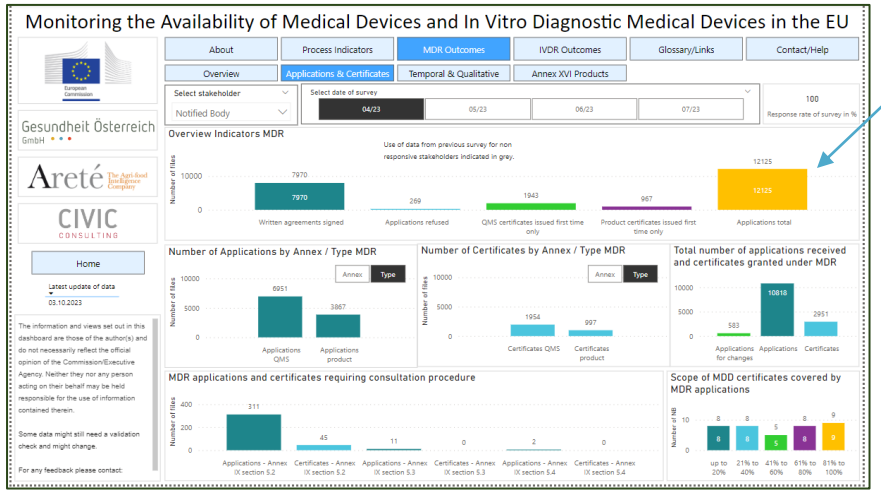
menu to navigate

interactive

expandable
(NB survey data already included)

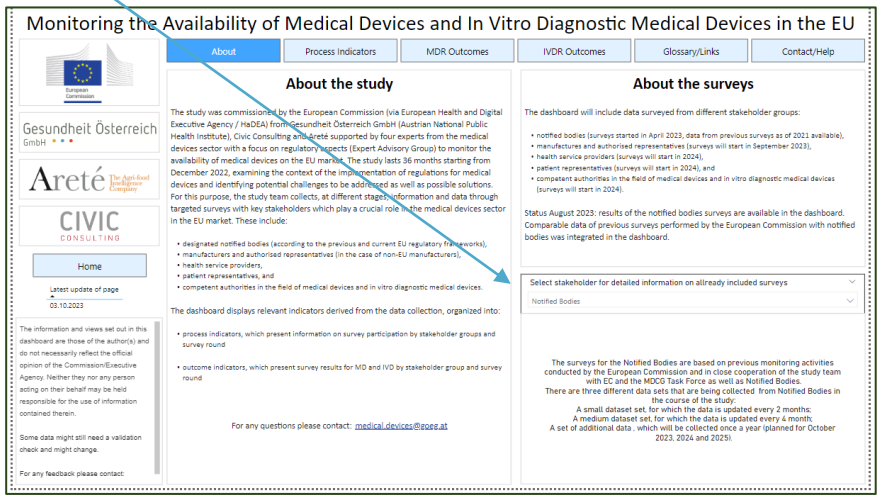
colorful graphs



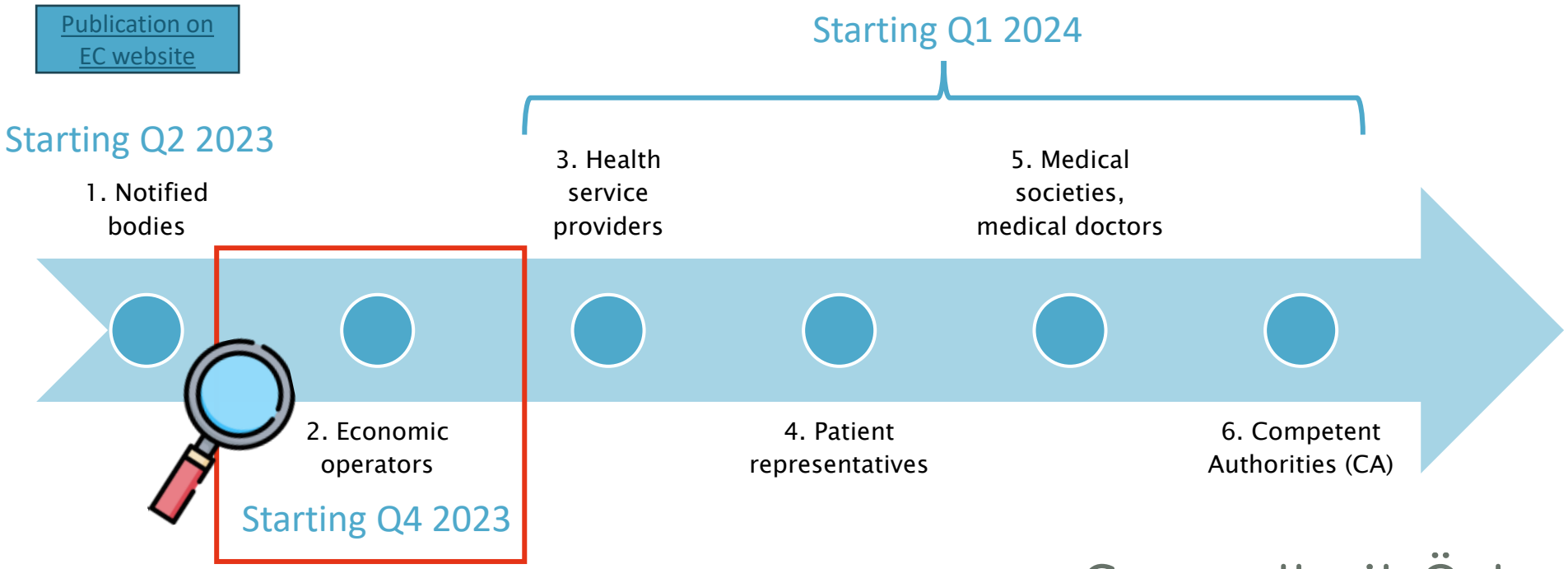


Results NB survey Publication on EC website

will be published soon: https://health.ec.europa.eu/medical-devices-topics-interest_en



2. Presentation of the survey



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Manufacturer & AR survey – survey tool

- **Tool**: EU survey
- **Deadline**: 15 January 2024 (23:59 CET)
- **Development of the survey:** The survey builds upon previous surveys conducted in this field and was developed together with DG SANTE and the MDCG TF on certification capacity monitoring and industry representatives.
- **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**

Recurring survey!

Manufacturer survey – content

Please only provide one answer per company!

IVD – same questions

AR – Separate questions

MD

- About the company (e.g. country, roles, SME, etc.)
- AIMDD/MDD – e.g.
  - no. of devices with (AI)MDD certificates; no. of (AI)MDD certificates;
  - no. of devices planned to transition to MDR and reasons why not
- Notified body (NB) – e.g.
  - If they have written agreements with a NB and reasons why not; no. of written agreements
  - If the NB refused applications and reasons for refusal
- MDR implementation – e.g.
  - Applications: no. of applications filed per Annex; How many devices are still under review?
  - Certificates: no. of devices covered by certificates in total & per class & new devices; no. of certificates per Annex
- Estimates – e.g.:
  - average cost for certification
  - percentage of total portfolio that requires a MDR certificate with an already received MDR certificate;
  - applications planned for new devices in the next 12-18 months
- Discontinued devices
- Preparedness of manufacturers

Manufacturer & AR 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

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

We apologise, we know it is a long survey, but we need your support!

3. EUSurvey tool

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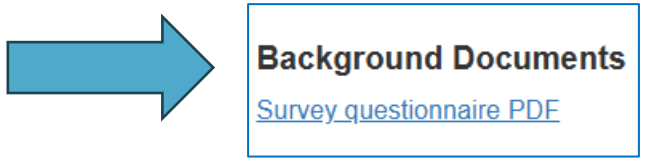
Key instructions

- Navigate through the questionnaire using “next” button at the end of each page. 

- To change a reply, it is sufficient to go back to the question and modify it.
- You can download the **full questionnaire** anytime by clicking on the button “Survey questionnaire PDF”.



- 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.

Additional tips

Please pay **specific attention** to:

- Indicate your **contact details** at Question ID_01
- Indicate if you are registered in **EUDAMED** at question ID_03
- The correct **role of your company** at Question ID_07 → on the basis of this reply, the correct set of questions that are relevant for your company will be displayed

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**)*

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. Questions and answers

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Thank you for participating to the survey!

Link: https://ec.europa.eu/eusurvey/runner/MFandAR

Deadline: 15 January 2024 (23:59 CET)

Contact: medical.devices@goeg.at

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