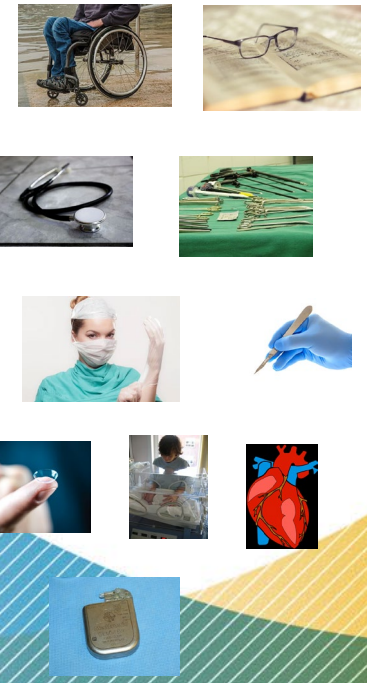
Study supporting the monitoring of availability of medical devices on the EU market (HaDEA/2021/P3/03)



Dialogforum MT
23 February 2024, 9.45-10.15

Friederike Windisch, Katharina Habimana

Online via MS Teams

Areté The Agri-food Intelligence Company

CIVIC CONSULTING

Gesundheit Österreich GmbH

Content

1. Brief study overview
2. Presentation of study-related dashboard

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: 30 countries (27 EU Member States plus Iceland, Liechtenstein and Norway)

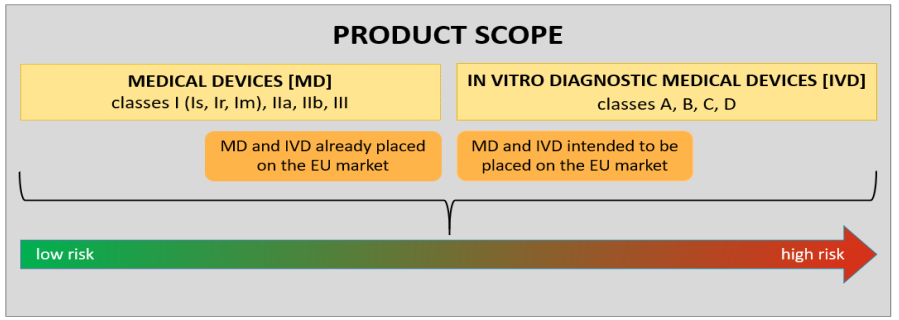
Duration:
2 December 2022 – 1 December 2025 (36 months)

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

Scope of the study



Source: GÖG

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 Member States plus Iceland, Liechtenstein and Norway as new regulations cover the EEA)

Consultation activities and presentation of results

Surveys

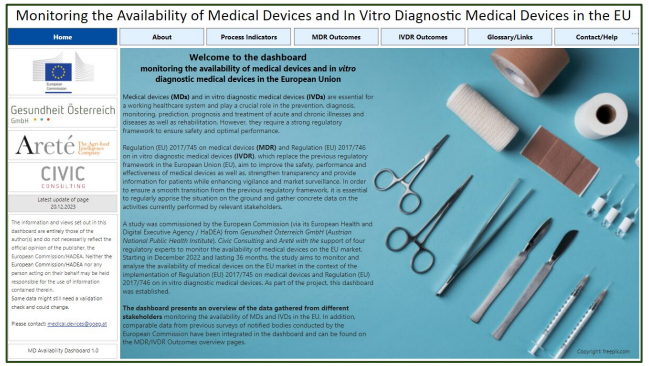
Interviews

MDCG Taskforce Meetings

Source Icons:
https://www.flaticon.com/de/kostenlose-icons/fragebogen
https://www.flaticon.com/de/kostenlose-icons/interview
https://www.flaticon.com/de/kostenlose-icons/diskussion

Results are presented in aggregated form in a **publicly available** and regularly updated dashboard

Published on **9 January 2024** and available at:
https://health.ec.europa.eu/study-supporting-monitoring-availability-medical-devices-eu-market_en



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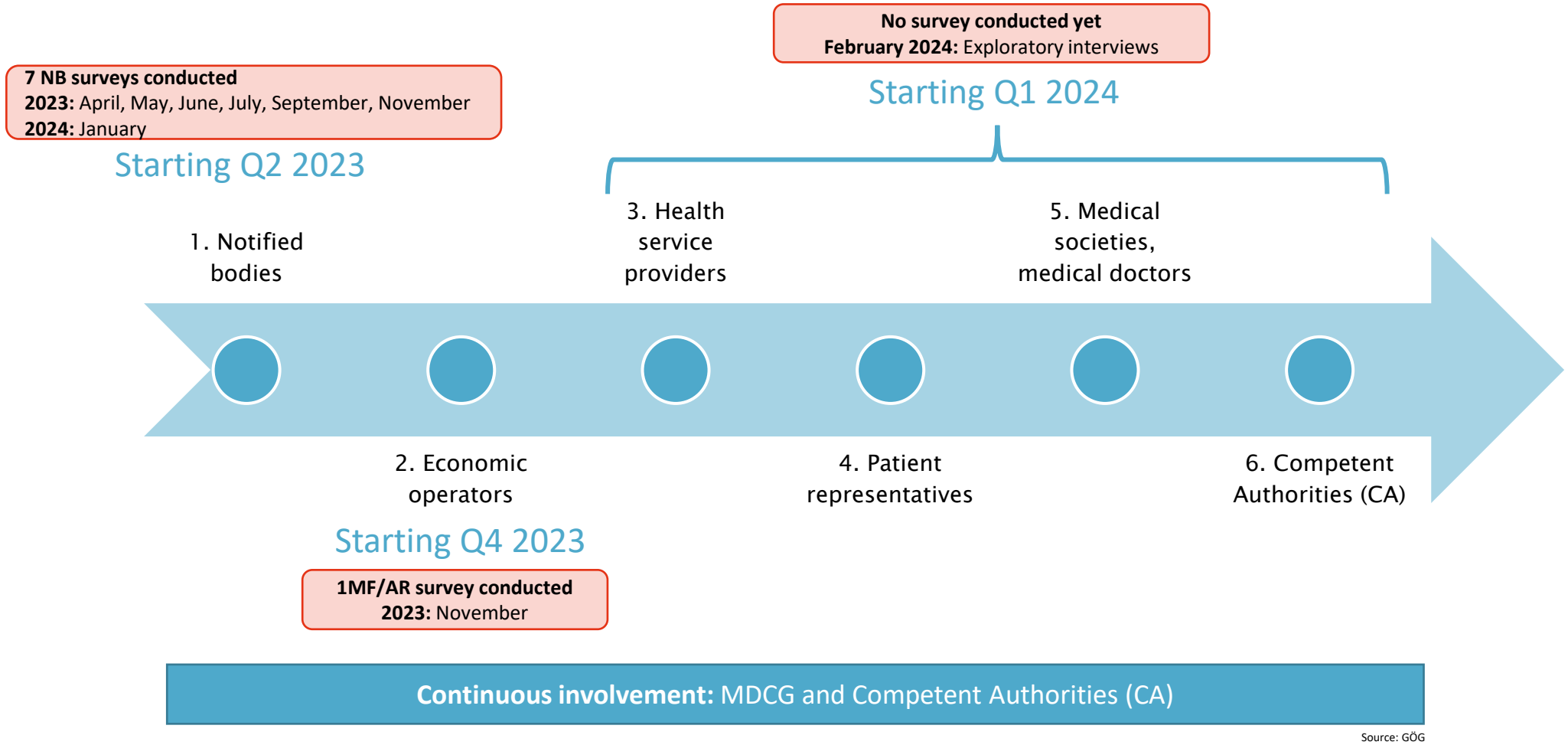
Overview of ongoing and planned survey activities



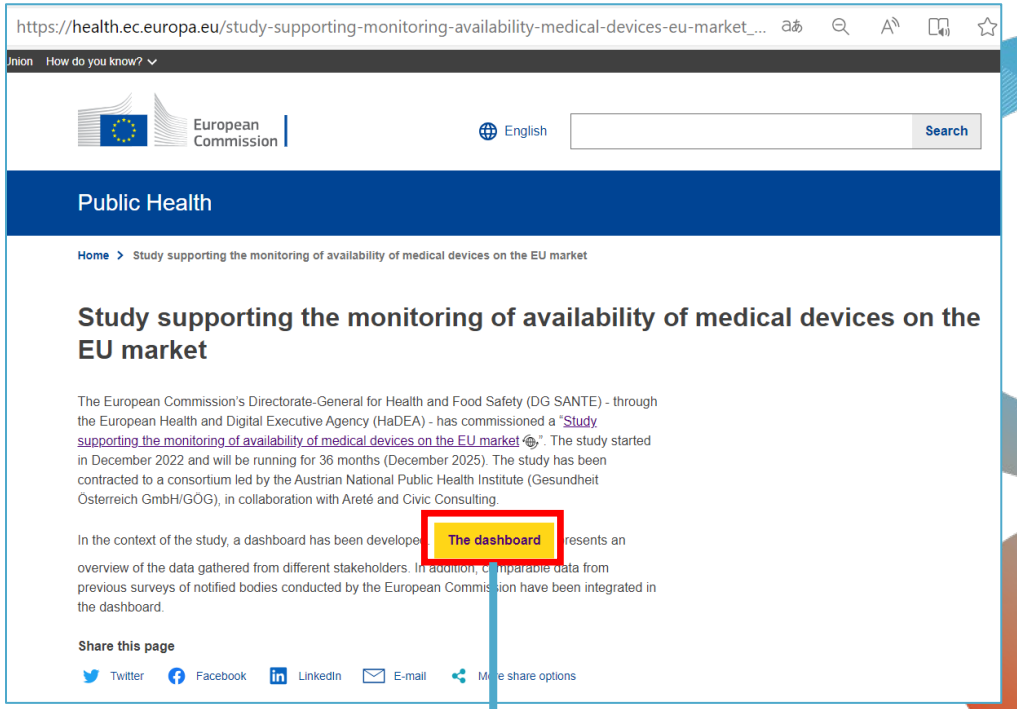
Source: GÖG

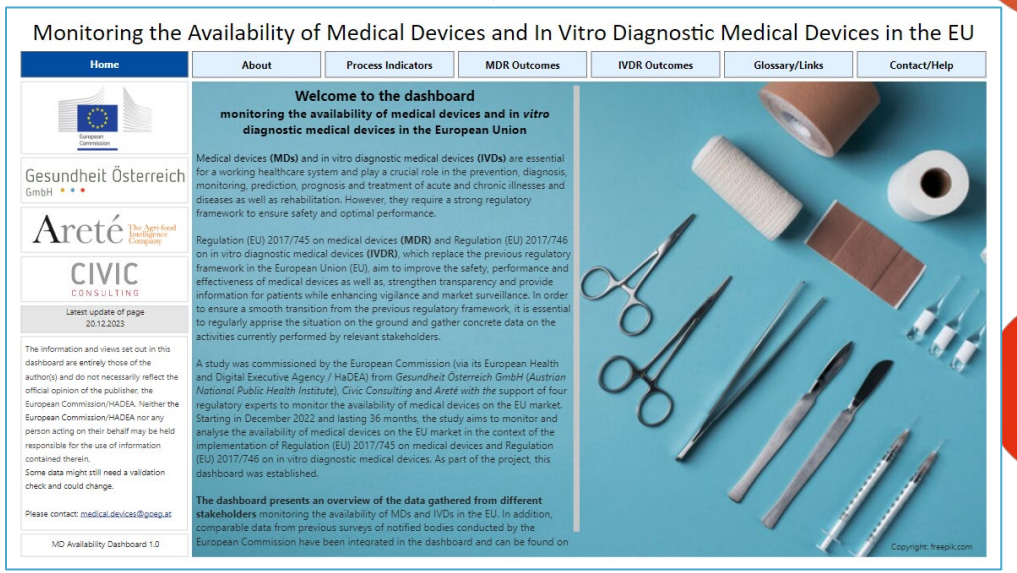
Dashboard

- **Publication** of study-related dashboard:
  9 January 2024

- **Link to the dashboard**
  - **Link to the study:** https://health.ec.europa.eu/study-supporting-monitoring-availability-medical-devices-eu-market_en (yellow button with link to the dashboard)
  - **Link to the published dashboard:** Microsoft Power BI

- **Content (23/02/2024):**
  - Results of five notified body surveys *(March 2023, April 2023, May 2023, June 2023, August 2023)*
  - Data available from previous surveys starting in 2021





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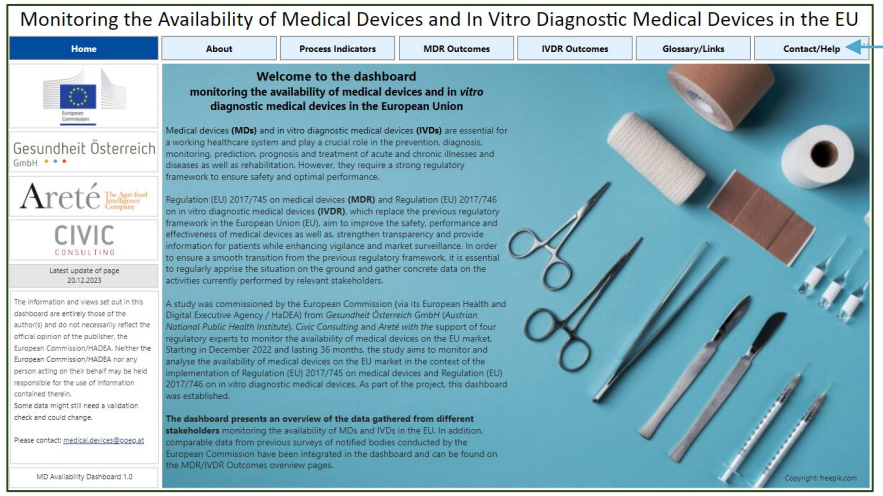
Dashboard (MS Power BI)

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

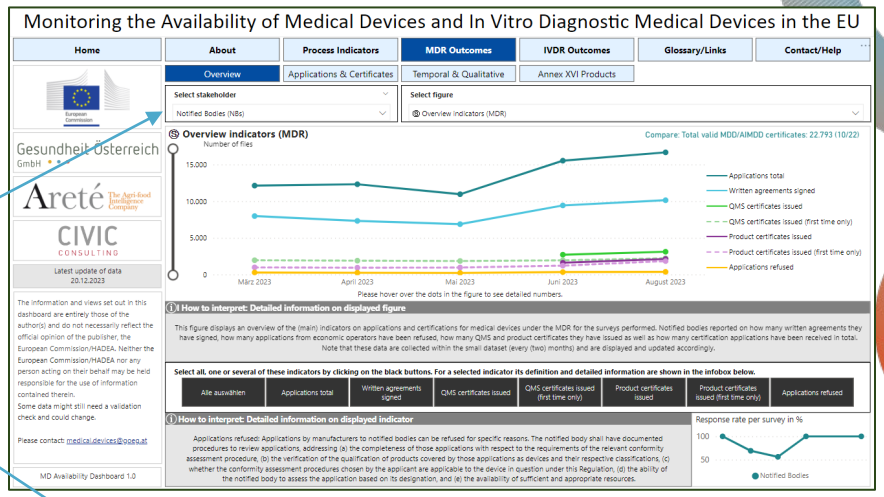


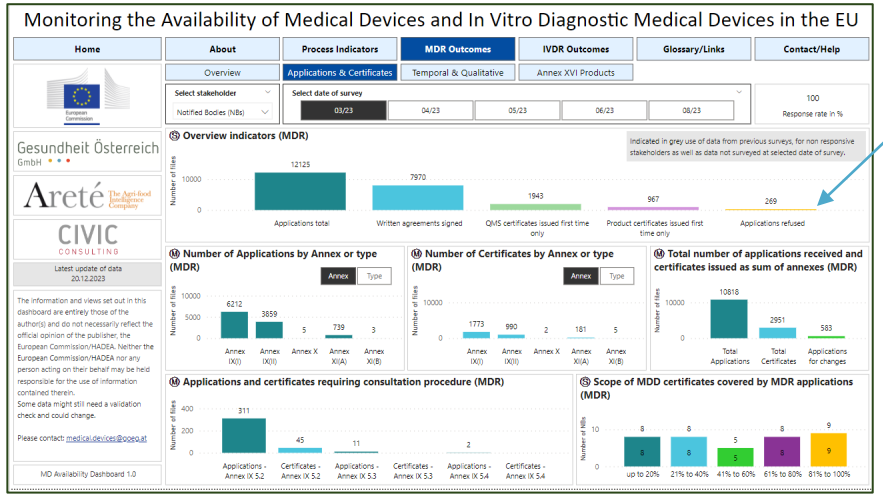
menu to navigate

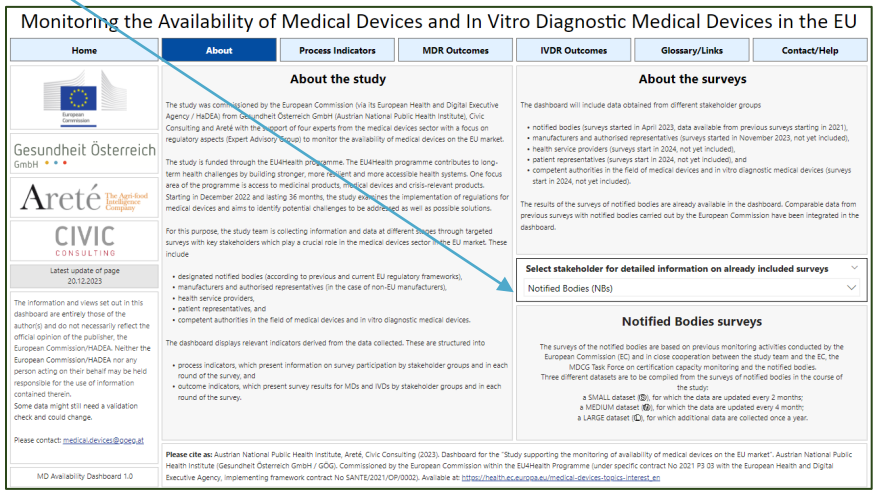
interactive

expandable
(NB survey data already included)

colorful graphs







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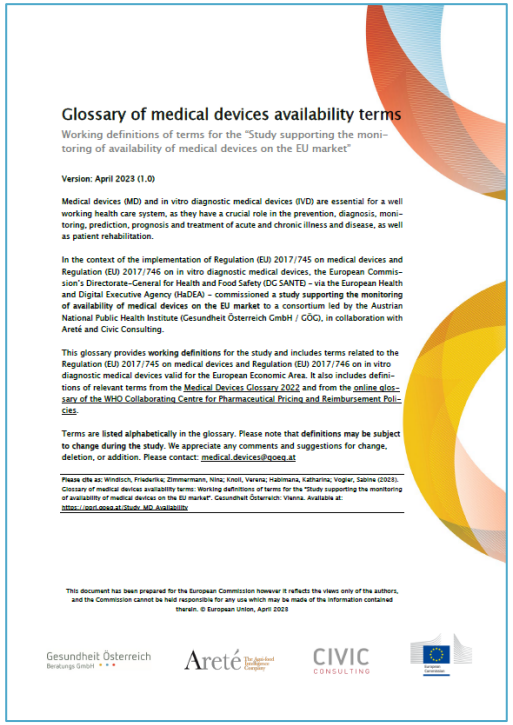
Supporting tools

Brief glossary



Glossary of medical devices availability terms

Working definitions of terms for the "Study supporting the monitoring of availability of medical devices on the EU market"

Version: April 2023 (1.0)

Medical devices (MD) and in vitro diagnostic medical devices (IVD) are essential for a well working health care system, as they have a crucial role in the prevention, diagnosis, monitoring, prediction, prognosis and treatment of acute and chronic illness and disease, as well as patient rehabilitation.

In the context of the implementation of Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices, the European Commission's Directorate-General for Health and Food Safety (DG SANTE) – via the European Health and Digital Executive Agency (HaDEA) – commissioned a study supporting the monitoring of availability of medical devices on the EU market to a consortium led by the Austrian National Public Health Institute (Gesundheit Österreich GmbH / GÖG), in collaboration with Areté and Civic Consulting.

This glossary provides working definitions for the study and includes terms related to the Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices valid for the European Economic Area. It also includes definitions of relevant terms from the Medical Devices Glossary 2022 and from the online glossary of the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies.

Terms are listed alphabetically in the glossary. Please note that definitions may be subject to change during the study. We appreciate any comments and suggestions for change, deletion, or addition. Please contact: medical.devices@goeg.at

Please cite as: Windisch, Friederike; Zimmermann, Nina; Knoll, Verena; Habimana, Katharina; Vogler, Sabine (2023). Glossary of medical devices availability terms: Working definitions of terms for the "Study supporting the monitoring of availability of medical devices on the EU market". Gesundheit Österreich: Vienna. Available at: https://pori.goeg.at/Study_MD_Availability

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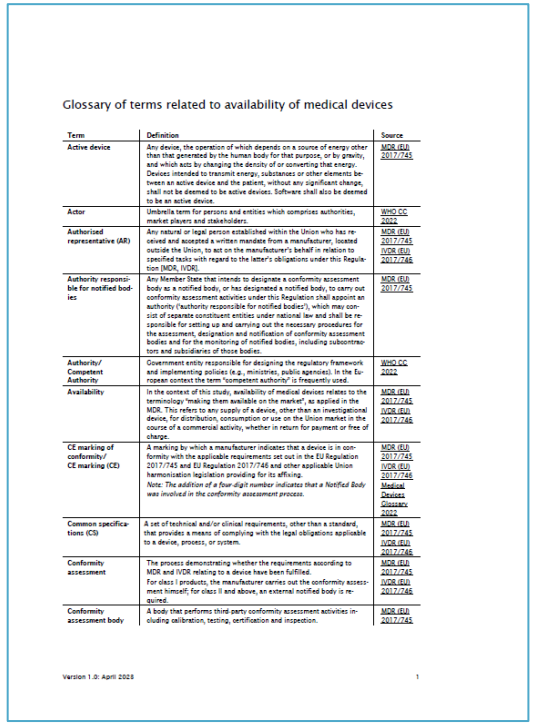

Glossary of terms related to availability of medical devices

Term	Definition	Source
Active device	Any device, the operation of which depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be deemed to be active devices. Software shall also be deemed to be an active device.	MDR (EU) 2017/745
Actor	Umbrella term for persons and entities which comprises authorities, market players and stakeholders.	WHO CC 2022
Authorised representative (AR)	Any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Regulation [MDR, IVDR].	MDR (EU) 2017/745 IVDR (EU) 2017/746
Authority responsible for notified bodies	Any Member State that intends to designate a conformity assessment body as a notified body, or has designated a notified body, to carry out conformity assessment activities under this Regulation shall appoint an authority ('authority responsible for notified bodies'), which may consist of separate constituent entities under national law and shall be responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, including subcontractors and subsidiaries of those bodies.	MDR (EU) 2017/745
Authority/ Competent Authority	Government entity responsible for designing the regulatory framework and implementing policies (e.g., ministries, public agencies). In the European context the term "competent authority" is frequently used.	WHO CC 2022
Availability	In the context of this study, availability of medical devices relates to the terminology "making them available on the market", as applied in the MDR. This refers to any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge.	MDR (EU) 2017/745 IVDR (EU) 2017/746
CE marking of conformity/ CE marking (CE)	A marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in the EU Regulation 2017/745 and EU Regulation 2017/746 and other applicable Union harmonization legislation providing for its affixing. *Note: The addition of a four-digit number indicates that a Notified Body was involved in the conformity assessment process.*	MDR (EU) 2017/745 IVDR (EU) 2017/746 Medical Devices Glossary 2022
Common specifications (CS)	A set of technical and/or clinical requirements, other than a standard, that provides a means of complying with the legal obligations applicable to a device, process, or system.	MDR (EU) 2017/745 IVDR (EU) 2017/746
Conformity assessment	The process demonstrating whether the requirements according to MDR and IVDR relating to a device have been fulfilled. For class I products, the manufacturer carries out the conformity assessment himself; for class II and above, an external notified body is required.	MDR (EU) 2017/745 IVDR (EU) 2017/746
Conformity assessment body	A body that performs third-party conformity assessment activities including calibration, testing, certification and inspection.	MDR (EU) 2017/745

Version 1.0: April 2023 1

Instructions for Use (for the dashboard)

Instructions for use

for the dashboard of the "Study supporting the monitoring of availability of medical devices on the EU market"

Version: November 2023 (1.0)

In the context of the implementation of Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices, the European Commission's Directorate-General for Health and Food Safety (DG SANTE) – via the European Health and Digital Executive Agency (HaDEA) – commissioned a study supporting the monitoring of availability of medical devices on the EU market to 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 is to monitor and analyse the availability of medical devices on the EU market in the context of the implementation of Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices. To that purpose, comprehensive surveys are conducted with various stakeholder groups (notified bodies, manufacturers and authorised representatives, health service providers, patient representatives, medical societies and medical doctors, Competent Authorities).

The study team has also designed a dashboard which contains aggregated data from the stakeholder surveys and is updated regularly.

The data, definitions, and additional comments for these "Instructions for use" have been drawn up by the MDCG TF on notified body capacity monitoring to support the interpretation of the data in the dashboard. The study team finalised this document with the accompanying text and design. This document has been reviewed by DG SANTE.

Terms are listed alphabetically. Please note that definitions and comments may be subject to change during the study.

We appreciate any comments and suggestions for change, deletion, or addition. Please contact: medical.devices@goeg.at

Please cite as: Caiffa, Virginia; Chiumia, Caroline; Windisch, Friederike; Zimmermann, Nina; Knoll, Verena (2023). Instructions for use for the "Study supporting the monitoring of availability of medical devices on the EU market". Gesundheit Österreich: Vienna. Available at: https://pori.goeg.at/Study_MD_Availability

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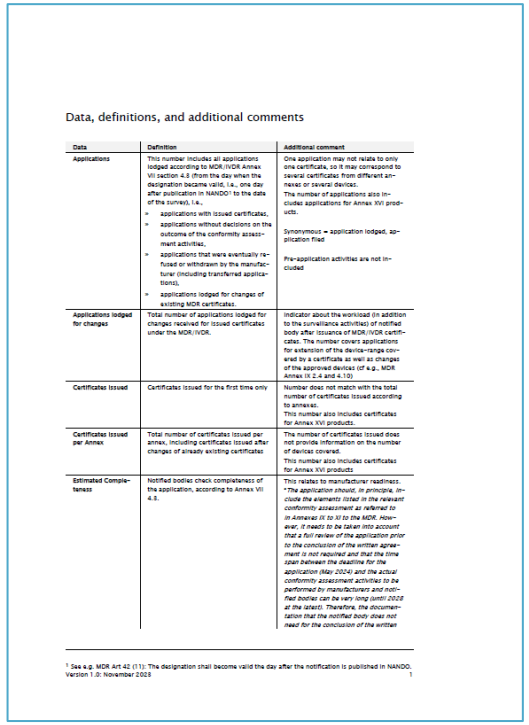

Data, definitions, and additional comments

Data	Definition	Additional comment
Applications	This number includes all applications lodged according to MDR/IVDR Annex VII section 4.8 (from the day when the designation became valid, i.e., one day after publication in NANDO[1] to the date of the survey), i.e., » applications with issued certificates, » applications without decisions on the outcome of the conformity assessment activities, » applications that were eventually refused or withdrawn by the manufacturer (including transferred applications), » applications lodged for changes of existing MDR certificates.	One application may not relate to only one certificate, so it may correspond to several certificates from different annexes or several devices. The number of applications also includes applications for Annex XVI products. Synonymous – application lodged, application filed Pre-application activities are not included
Applications lodged for changes	Total number of applications lodged for changes received for issued certificates under the MDR/IVDR.	Indicator about the workload (in addition to the surveillance activities) of notified body after issuance of MDR/IVDR certificates. The number covers applications for extension of the device-range covered by a certificate as well as changes of the approved devices (cf e.g., MDR Annex IX 2.4 and 4.10)
Certificates issued	Certificates issued for the first time only	Number does not match with the total number of certificates issued according to annex xx. This number also includes certificates for Annex XVI products.
Certificates issued per Annex	Total number of certificates issued per annex, including certificates issued after changes of already existing certificates	The number of certificates issued does not provide information on the number of devices covered. This number also includes certificates for Annex XVI products
Estimated Completeness	Notified bodies check completeness of the application, according to Annex VII 4.8.	This relates to manufacturer readiness. *[2]The application should, in principle, include the elements listed in the relevant conformity assessment as referred to in Annexes IX to XI to the MDR. However, it needs to be taken into account that a full review of the application prior to the conclusion of the written agreement is not required and that the time span between the deadline for the application (May 2024) and the actual conformity assessment activities to be performed by manufacturers and notified bodies can be very long (until 2028 at the latest). Therefore, the documentation that the notified body does not need for the conclusion of the written*

[1] See e.g. MDR Art 42 (11): The designation shall become valid the day after the notification is published in NANDO.

Version 1.0: November 2023 1

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Thank you for your attention!

Please contact the study team in case of questions, suggestions or comments!

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

Key contacts DG SANTE/HaDEA:
Ms Maria Chiara Orlandi (DG SANTE)
Ms Erica Poot (HaDEA)