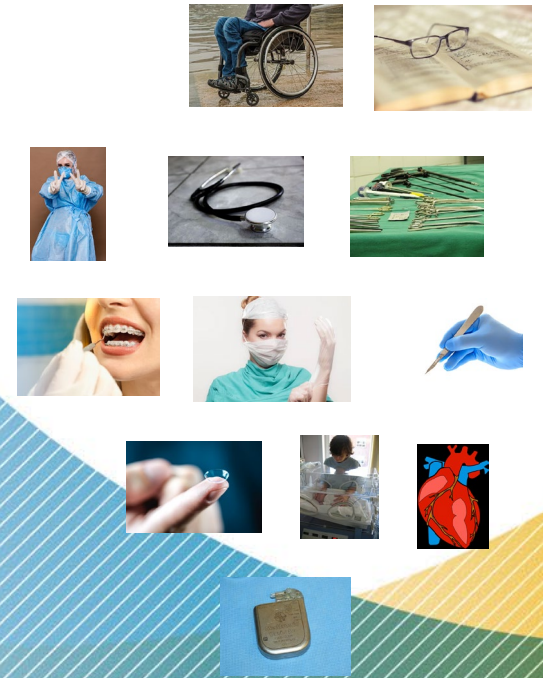


# Study supporting the monitoring of availability of medical devices on the EU market (HaDEA/2021/P3/03)

Dialogforum MT  
23 February 2024, 9.45-10.15

Friederike Windisch, Katharina Habimana

Online via MS Teams



# 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)

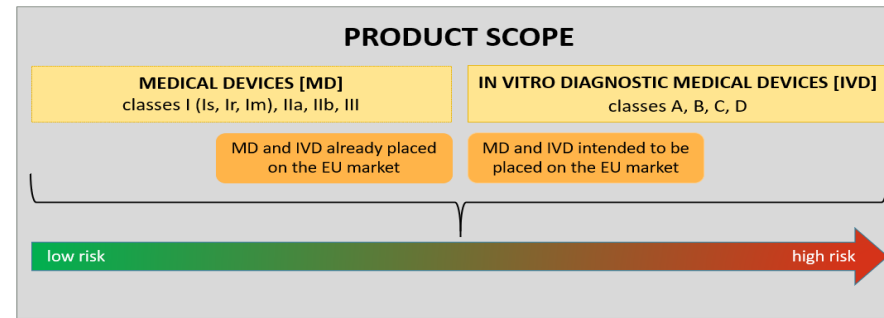
## Study team:

- **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](mailto:medical.devices@goeg.at)

# Scope of the study

## Product scope:



Source: GÖG

- **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)

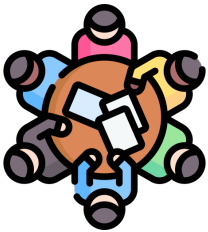
# Consultation activities and presentation of results



Surveys



Interviews

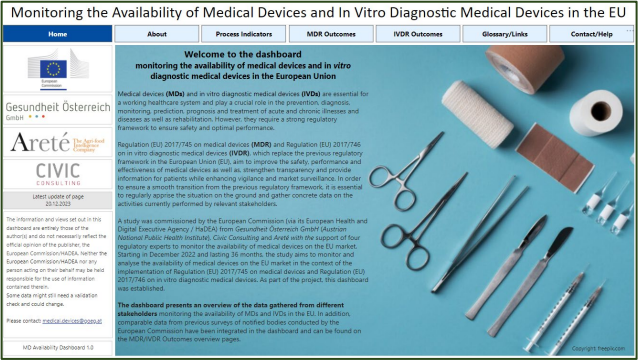


MDCG Taskforce Meetings

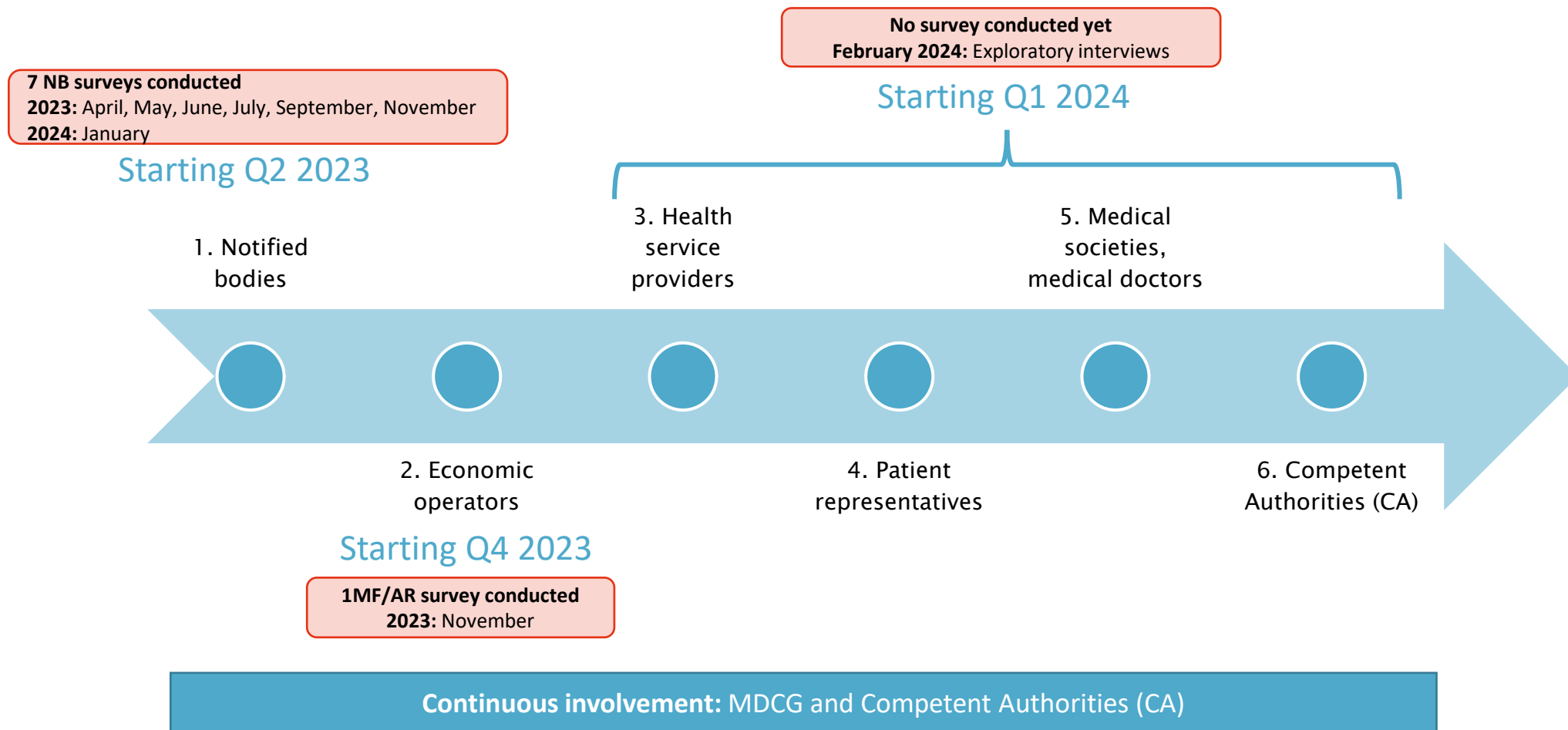
Results are presented in aggregated form in a publicly available and regularly updated dashboard

Published on 9 January 2024 and available at:  
[https://health.ec.europa.eu/study-supporting-monitoring-availability-medical-devices-eu-market\\_en](https://health.ec.europa.eu/study-supporting-monitoring-availability-medical-devices-eu-market_en)

Source Icons:  
<https://www.flaticon.com/de/kostenlose-icoms/fragebogen>  
<https://www.flaticon.com/de/kostenlose-icoms/interview>  
<https://www.flaticon.com/de/kostenlose-icoms/diskussion>



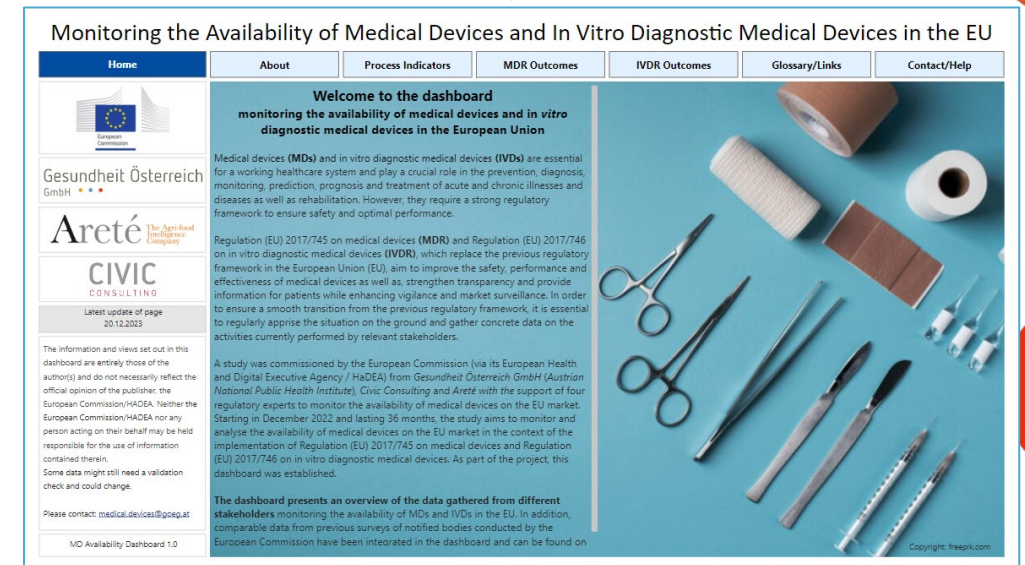
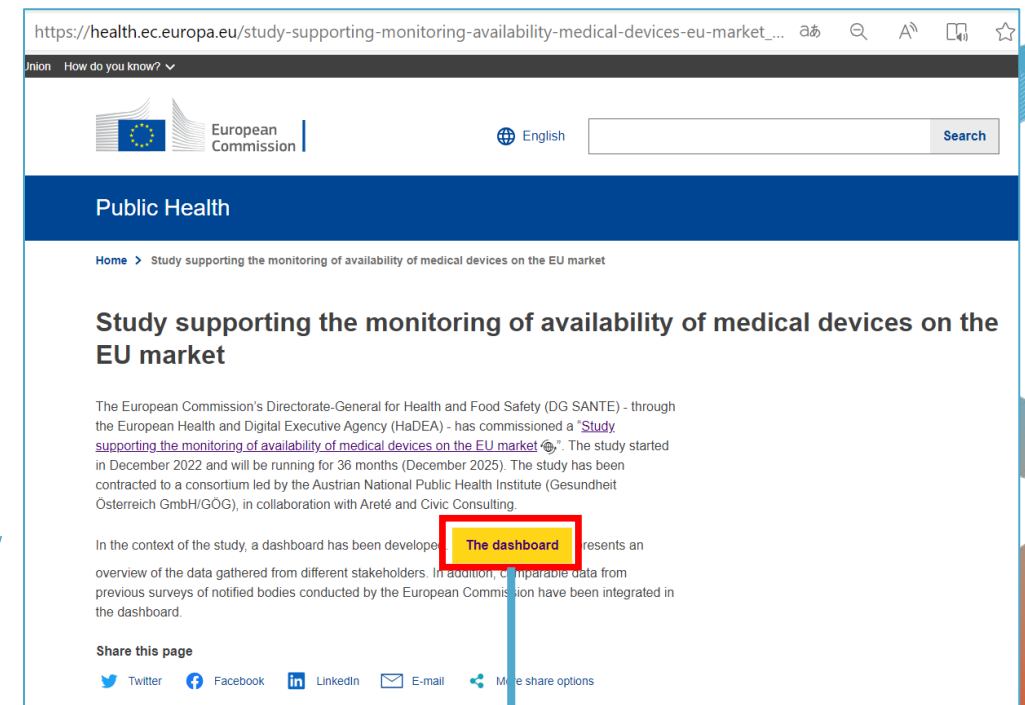
# Overview of ongoing and planned survey activities



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](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



# 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

**Monitoring the Availability of Medical Devices and In Vitro Diagnostic Medical Devices in the EU**

Home | About | Process Indicators | MDR Outcomes | IVDR Outcomes | Glossary/Links | Contact/Help

Welcome to the dashboard monitoring the availability of medical devices and in vitro diagnostic medical devices in the European Union

Medical devices (MDs) and in vitro diagnostic medical devices (IVDs) are essential for a working healthcare system and play a crucial role in the prevention, diagnosis, monitoring, prediction, prognosis and treatment of acute and chronic illnesses and diseases as well as rehabilitation. However, they require a strong regulatory framework to ensure safety and optimal performance.

Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR), which replace the previous regulatory framework in the European Union (EU), aim to improve the safety, performance and effectiveness of medical devices as well as, strengthen transparency and provide information for patients while enhancing vigilance and market surveillance. In order to ensure a smooth transition from the previous regulatory framework, it is essential to regularly appraise the situation on the ground and gather concrete data on the activities currently performed by relevant stakeholders.

A study was commissioned by the European Commission (via its European Health and Digital Executive Agency / HaDEA) from *Gesundheit Österreich GmbH* (Austrian National Public Health Institute), *Civic Consulting and Areté* with the support of four regulatory experts to monitor the availability of medical devices on the EU market. Starting in December 2022 and lasting 36 months, the study aims 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. As part of the project, this dashboard was established.

The dashboard presents an overview of the data gathered from different stakeholders monitoring the availability of MDs and IVDs in the EU. In addition, comparable data from previous surveys of notified bodies conducted by the European Commission have been integrated in the dashboard and can be found on the MDR/IVDR Outcomes overview pages.

Latest update of page: 20.12.2023

The information and views set out in this dashboard are entirely those of the author(s) and do not necessarily reflect the official opinion of the publisher, the European Commission/HADEA. Neither the European Commission/HADEA nor any person acting on their behalf may be held responsible for the use of information contained therein. Some data might still need a validation check and could change.

Please contact: [medical.devices@oepa.at](mailto:medical.devices@oepa.at)

MD Availability Dashboard 1.0

menu to navigate

interactive

expandable  
(NB survey data already included)

**Monitoring the Availability of Medical Devices and In Vitro Diagnostic Medical Devices in the EU**

Home | About | Process Indicators | MDR Outcomes | IVDR Outcomes | Glossary/Links | Contact/Help

Overview | Applications & Certificates | Temporal & Qualitative | Annex XVI Products

Select stakeholder: *Gesundheit Österreich GmbH*

Select figure: Overview indicators (MDR)

Compare: Total valid MDD/AMDD certificates: 22.793 (10/22)

Number of files

Overview indicators (MDR)

12,125 Applications total  
7,970 Written agreements signed  
1,943 QMS certificates issued (first time only)  
967 Product certificates issued (first time only)  
269 Applications refused

How to interpret: Detailed information on displayed figure

This figure displays an overview of the (main) indicators on applications and certifications for medical devices under the MDR for the surveys performed. Notified bodies reported on how many written agreements they have signed, how many applications from economic operators have been refused, how many QMS and product certificates they have issued as well as how many certification applications have been received in total. Note that these data are collected within the annual dataset (every two months) and are displayed and updated accordingly.

Select all, one or several of these indicators by clicking on the black buttons. For a selected indicator its definition and detailed information are shown in the info box below.

All submission | Applications total | Written agreements signed | QMS certificates issued | QMS certificates issued (first time only) | Product certificates issued | Product certificates issued (first time only) | Applications refused

How to interpret: Detailed information on displayed indicator

Applications refused: Applications by manufacturers to notified bodies can be refused for specific reasons. The notified body shall have documented procedures to review applications, addressing (a) the completeness of those applications with respect to the requirements of the relevant conformity assessment procedure, (b) the verification of the qualification of products covered by those applications as devices and their respective classifications, (c) whether the conformity assessment procedures chosen by the applicant are applicable to the device in question under this Regulation, (d) the ability of the notified body to assess the application based on its designation, and (e) the availability of sufficient and appropriate resources.

Response rate per survey in %

100  
50  
0

Notified Bodies

Latest update of data: 20.12.2023

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MD Availability Dashboard 1.0

colorful graphs

**Monitoring the Availability of Medical Devices and In Vitro Diagnostic Medical Devices in the EU**

Home | About | Process Indicators | MDR Outcomes | IVDR Outcomes | Glossary/Links | Contact/Help

Overview | Applications & Certificates | Temporal & Qualitative | Annex XVI Products

Select stakeholder: *Gesundheit Österreich GmbH*

Select date of survey: 09/23 | 04/23 | 05/23 | 06/23 | 08/23

Response rate in %: 100

Overview indicators (MDR)

12,125 Applications total  
7,970 Written agreements signed  
1,943 QMS certificates issued first time only  
967 Product certificates issued first time only  
269 Applications refused

Number of Applications by Annex or type (MDR)

Annex	Type	Number of files
Annex (IX)	Annex (IX)	6212
Annex (X)	Annex (X)	3859
Annex (X)	Annex (X)	5
Annex (X)	Annex (X)	739
Annex (X)	Annex (X)	3

Number of Certificates by Annex or type (MDR)

Annex	Type	Number of files
Annex (IX)	Annex (IX)	1773
Annex (X)	Annex (X)	990
Annex (X)	Annex (X)	2
Annex (X)	Annex (X)	181
Annex (X)	Annex (X)	5

Total number of applications received and certificates issued as sum of annexes (MDR)

Category	Number of files
Total Applications	10816
Total Certificates	2951
Applications for changes	583

Applications and certificates requiring consultation procedure (MDR)

Annex	Type	Number of files
Annex (X 5.2)	Certificates	311
Annex (X 5.2)	Applications	45
Annex (X 5.3)	Certificates	11
Annex (X 5.3)	Applications	2
Annex (X 5.4)	Certificates	2
Annex (X 5.4)	Applications	0

Scope of MDD certificates covered by MDR applications (MDR)

Percentage	Number of files
up to 20%	8
21% to 40%	8
41% to 60%	5
61% to 80%	9
81% to 100%	9

Latest update of data: 20.12.2023

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Please contact: [medical.devices@oepa.at](mailto:medical.devices@oepa.at)

MD Availability Dashboard 1.0

**Monitoring the Availability of Medical Devices and In Vitro Diagnostic Medical Devices in the EU**

Home | About | Process Indicators | MDR Outcomes | IVDR Outcomes | Glossary/Links | Contact/Help

About the study

The study was commissioned by the European Commission (via its European Health and Digital Executive Agency / HADEA) from *Gesundheit Österreich GmbH* (Austrian National Public Health Institute), *Civic Consulting* and *Areté* with the support of four experts from the medical devices sector with a focus on regulatory aspects (Expert Advisory Board) to monitor the availability of medical devices on the EU market.

The study is funded through the EU4Health programme. The EU4Health programme contributes to long-term health challenges by building stronger, more resilient and more accessible health systems. One focus area of the programme is access to medical products, medical devices and crisis-relevant products. Starting in December 2022 and lasting 36 months, the study analyses the implementation of regulations for medical devices and aims to identify potential challenges to be addressed as well as possible solutions.

For this purpose, the study team is collecting information and data at different stages through targeted surveys with key stakeholders which play a crucial role in the medical devices sector on the EU market. These include:

- designated notified bodies (according to previous and current EU regulatory frameworks),
- manufacturers and authorised representatives (in the case of non-EU manufacturers),
- health service providers,
- patient representatives, and
- competent authorities in the field of medical devices and in vitro diagnostic medical devices.

The dashboard displays relevant indicators derived from the data collected. These are structured into:

- process indicators, which present information on survey participation by stakeholder groups and in each round of the survey, and
- outcome indicators, which present survey results for MDs and IVDs by stakeholder groups and in each round of the survey.

Some data might still need a validation check and could change.

Please contact: [medical.devices@oepa.at](mailto:medical.devices@oepa.at)

MD Availability Dashboard 1.0

About the surveys

The dashboard will include data obtained from different stakeholder groups:

- notified bodies (surveys started in April 2023, data available from previous surveys starting in 2021),
- manufacturers and authorised representatives (surveys started in November 2023, not yet included),
- health service providers (surveys start in 2024, not yet included),
- patient representatives (surveys start in 2024, not yet included), and
- competent authorities in the field of medical devices and in vitro diagnostic medical devices (surveys start in 2024, not yet included).

The results of the surveys of notified bodies are already available in the dashboard. Comparable data from previous surveys with notified bodies carried out by the European Commission have been integrated in the dashboard.

Select stakeholder for detailed information on already included surveys

Notified Bodies (NBs)

Notified Bodies surveys

The surveys of the notified bodies are based on previous monitoring activities conducted by the European Commission (EC) and in close cooperation between the study team and the EC, the MDG Task Force on certification capacity monitoring and the notified bodies. Three different datasets are to be compiled from the surveys of notified bodies in the course of the study:

- a SMALL dataset (S), for which the data are updated every 2 months;
- a MEDIUM dataset (M), for which the data are updated every 4 months;
- a LARGE dataset (L), for which additional data are collected once a year.

Please cite as: Austrian National Public Health Institute, Areté, Civic Consulting (2023), dashboard for the 'Study' supporting the monitoring of availability of medical devices on the EU market. Austrian National Public Health Institute (Gesundheit Österreich GmbH / GÖG), Commissioned by the European Commission within the EU4Health Programme under specific contract No 2021 PS 03 with the European Health and Digital Executive Agency, implementing framework contract No SANTE/2021/OP/0002. Available at: [https://health.ec.europa.eu/medical-devices-tools/index\\_en](https://health.ec.europa.eu/medical-devices-tools/index_en)



# 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@goe.at](mailto:medical.devices@goe.at)

Please cite as: Windisch, Friederike, Zimmermann, Nina, Kroll, Verena, Radomka, Katharina, Vogler, Sabine (2023). Glossary of medical device 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://contape.at/Study\\_MD\\_Availability](https://contape.at/Study_MD_Availability)

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Areté  
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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.	MHO 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 specific tasks with regard to the latter's obligations under this Regulation (MDR, IVD).	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.	MHO 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 in the Union market in the course of a commercial activity, whether in return for payment or free of charge.	MDR (EU) 2017/745 2017/746 IVDR (EU) 2017/746 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 2017/746 IVDR (EU) 2017/746 2017/746 2017/746
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 2017/746 IVDR (EU) 2017/746 2017/746
Conformity assessment	The process demonstrating whether the requirements according to MDR and IVD 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 2017/746 IVDR (EU) 2017/746 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

## 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 MDCC ITF 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@goe.at](mailto:medical.devices@goe.at)

Please cite as: Calla, Virginia, Chumita, Carolina, Windisch, Friederike, Zimmermann, Nina, Kroll, 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://contape.at/Study\\_MD\\_Availability](https://contape.at/Study_MD_Availability)

Gesundheit Österreich  
Areté  
CIVIC CONSULTING

**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) 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 rejected 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, as it may correspond to several certificates from different annexes or several devices. The number of applications also includes applications for Annex VIII products. Synonymous = application lodged, application filed Pre-application activities are not included
Applications lodged for changes	Total number of applications lodged for changes required for issued certificates under the MDR/IVDR.	Indicator about the withdrawal (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 (e.g., MDR Annex IX 2.a and IX 3)
Certificate issued	Certificates issued for the first time only	Number does not match with the total number of certificates issued according to annexes. This number also includes certificates for Annex VIII products.
Certificate 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 VIII products.
Estimated Completeness	Notified bodies check completeness of the application, according to annex VII 4.8.	This relates to manufacturer readiness. The application should, in principle, include the annexes listed in the relevant conformity assessment as referred to in Annex IX 10 to 13 of 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 2020) and the actual conformity assessment activities to be performed by manufacturers and notified bodies can be very long (until 2024 at the latest). Therefore, the documentation that the notified body does not need for the conclusion of the written

<sup>1</sup> See e.g. MDR Art 42 (1). The designation shall become valid the day after the notification is published in NANDO.  
Version 1.0: November 2023



# Thank you for your attention!

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

## **Project manager:**

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