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: Gaiffe, Virginie; 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://ppri.goeg.at/Study_MD_Availability

Gesundheit Österreich GmbH · Areté The Agri-food Intelligence Company · CIVIC CONSULTING · European Commission

Data, definitions, and additional comments

Data	Definition	Additional comment
Applications	This number includes all applications lodged according to MDR/IVDR Annex VII section 4.3 (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 annexes. 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 4.3.	This relates to manufacturer readiness. "*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.

Data	Definition	Additional comment
		agreement with the manufacturer and that is likely to be updated by the manufacturer before the actual conformity assessment does not need to be submitted with the application."[2] The estimated completeness can be identified in the "completeness check" made by NB. This data is an estimated percentage of applications which were deemed satisfactory in terms of documentation provided (before undertaking the review of its content) without requesting for any additional information.
IVDR Product certificate	» EU technical documentation assessment certificates (Annex IX, chapter II) » EU type-examination certificates (Annex X)	The number or average number of devices covered by a certificate is not determined
IVDR QMS certificate	» EU quality management system certificates (Annex IX, chapter I) » EU quality assurance certificates (Annex XI)	The number or average number of devices covered by a certificate is not determined
MDR Product certificate	» EU technical documentation assessment certificates (Annex IX, chapter II) » EU type-examination certificates (Annex X) » EU product verification certificates (Annex XI, Part B)	The number or average number of devices covered by a certificate is not determined.
MDR QMS certificate	» EU quality management system certificates (Annex IX, chapter I) » EU quality assurance certificates (Annex XI, Part A)	The number or average number of devices covered by a certificate is not determined.
Number of Devices	Relates to number of devices by means of product code, catalogue number or other unambiguous reference allowing traceability.	
Reason for refusal	Reasons for refusing applications lodged under MDR	This relates both to manufacturer readiness and Notified body capacity. The number of applications lodged under MDR that have been refused, by reason of refusal, will be used in this context as an indicator.
Scope of MDD certificates covered by MDR applications	Rough estimation of the average scope covered by MDR application regarding scope of MDD certificate	Rough estimation of the average scope covered by MDR application regarding scope of MDD certificate: *meaning of scope coverage: MDD certificate covers 100 products, MDR application covers 50 products then coverage of the MDR = 50% of the MDD cert ** meaning of average:

[2] Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, REV. 1, JULY 2023.

Data	Definition	Additional comment
		MDR application n°1 covers 1 product on 10 (MDD cert) = 10% MDR application n°2 covers 50 products on 100 (MDD cert) = 50% MDR application n°3 covers 4 products on 12 (MDD cert) = 33% => so average % = 31% => between 21% and 40% Objective: to get an idea of the devices transitioning to MDR, not only certificates
Time to reach a new certificate	Time to reach issuance of a new EU certificate (from written agreement signed to issuance) under MDR.	
Timeframe between application lodged and written agreement signed	Time needed from "application lodged" until the signature of a written agreement by both parties.	
Written agreement	Contract between a notified body and a manufacturer signed by both parties in accordance with Annex VII section 4.3, second subparagraph of the MDR/IVDR.	One written agreement may relate to one or more applications as well as certificates (for the same or different annexes).