

Timetable for notified bodies surveys

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

Version: June 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.

For this purpose, the study team will collect information and data through **targeted surveys with key stakeholders** which play a crucial role in the availability of medical devices including notified bodies, manufacturers, and authorised representatives (in the case of non-EU manufacturers), as well as in a later stage health service providers and patient representatives. For surveying notified bodies **three different recurring surveys were developed** which alter in content, length, and frequency (small, medium, and large dataset).

To assist notified bodies in planning, this document lists all envisaged mailings and deadlines as well as the requested data set for the first study year 2023. **Please note that dates may also be modified due to changes in the project and the legal environment.**

If you have any questions or comments, please feel free to contact us via the e-mail-address medical.devices@goeg.at.

Survey timetable 2023¹

Month	Mailing	Deadline	Requested dataset		
			Small dataset	Medium dataset	Large dataset
April 2023	3 April	19 April ²	✓	✓	✗
May 2023	12 May	29 May	✓	✗	✗
June 2023	5 June	16 June	✓	✗	✗
July 2023	3 July	14 July	✓	✓	✗
August 2023	n. appl.	n. appl.	✗	✗	✗
September 2023	1 September	14 September	✓	✗	✗
October 2023	n. appl.	n. appl.	✗	✗	✗
November 2023	3 November	16 November	✓	✓	✓
December 2023	n. appl.	n. appl.	✗	✗	✗

¹ Changes possible at any time.

² The survey was completed on 5 May 2023.

n. appl. = not applicable

Please cite as: Windisch, Friederike; Zimmermann, Nina; Knoll, Verena (2023). Timetable for notified bodies surveys 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

Reviewed by: Vogler, Sabine (2023). Gesundheit Österreich; Gentile, Mario; Piccoli, Giannina; Del Prete, Margherita (2023). Areté