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Berlin, 14. April 2023

Confirmation of receipt of a formal application and conclusion of written agreement in the framework of Regulation EU 2023/607 amending Regulation (EU) 2017/745 as regards the transitional provisions for certain medical devices
Reference number: 22-100-S

To whom it may concern,

This letter confirms that, Berlin Cert Prüf- und Zertifizierstelle für Medizinprodukte GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0633 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the manufacturer listed above.

The devices covered by the formal application and the written agreement mentioned above are listed in Table 1 below.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer submitted the MDR application and signed the written agreement by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation/exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR by the 20 Mar 2023 for the relevant devices.

Digitally signed by Grabazei Alexandru
Date: 2023.11.08 15:31:06 EET
Reason: MoldSign Signature
Location: Moldova

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

Digital unterschrieben
von Martin Tettke
Datum: 2023.04.14
13:46:34 +02'00'

Dipl.-Ing. Martin Tettke

Head of Certification Body and Notified Body

Tabelle 1: devices covered by this letter

Device name / Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
HNO-Behandlungseinheit der Baureihe MEDICENTER	Class IIa	N/A	Certificate: Z-16-169-SZ-R II / Z-16-169-SZ-R II-E Notified Body number: 0633

Tabelle 2: revision history

Date	action
14 April 2023	Initial issue