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Berlin, 19. September 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: 23-143-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issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer submitted the MDR application and signed the written agreement by the date of MDD certificate expiry; or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.

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,

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
kabelloser EKG Holter Recorder - smart ECG 4260585220231	Class IIa	N/A	Certificate: Z-19-124-S-R II-N3 Notified Body number: 0633
kabelloser EKG Holter Recorder - liveECG-V2 4260585220194	Class IIa	N/A	Certificate: Z-19-124-S-R II-N3 Notified Body number: 0633
kabelloser EKG Holter Recorder - net_ECG SDX 4260585220255	Class IIa	N/A	Certificate: Z-19-124-S-R II-N3 Notified Body number: 0633
kabelloser EKG Holter Recorder - kECG-3 4260585220279	Class IIa	N/A	Certificate: Z-19-124-S-R II-N3 Notified Body number: 0633
kabelloser EKG Holter Recorder - kECG-1 4260585220262	Class IIa	N/A	Certificate: Z-19-124-S-R II-N3 Notified Body number: 0633
kabelloser EKG Holter Recorder - ECG Time-S 4260585220200	Class IIa	N/A	Certificate: Z-19-124-S-R II-N3 Notified Body number: 0633
kabelloser EKG Holter Recorder - dpv-ritmo III 4260585220248	Class IIa	N/A	Certificate: Z-19-124-S-R II-N3 Notified Body number: 0633
kabelloser EKG Holter Recorder - Cardioline ECG 4260585220224	Class IIa	N/A	Certificate: Z-19-124-S-R II-N3 Notified Body number: 0633
kabelloser EKG Holter Recorder - auxil ECG 4260585220217	Class IIa	N/A	Certificate: Z-19-124-S-R II-N3 Notified Body number: 0633

Tabelle 2: revision history

Date	action
19 September 2023	Initial issue