To whom it may concern

DNV MEDCERT GmbH
Pilatuspool 2
20355 Hamburg
Germany

Tel: +49 40 2263325-0
E-mail: Medcert-Info@dnv.com

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Notified Body Confirmation Letter
Certification No: 1320GB454240905

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework 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

To whom it may concern,

This letter confirms that DNV Medcert GmbH, a Notified Body (NB), designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0482 on Nando[1], 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 following manufacturer.

Andreas Fahl Medizintechnik-Vertrieb GmbH
August-Horch-Straße 4A
51149 Köln
Germany
SRN[2]: DE-MF-000006665

The devices covered by the formal application and the written agreement mentioned above are identified in the tables (in the appendix of this letter). Table 1 identifies the devices for which an MDR application has been received, a written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by 20 March 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 120.3c of MDR (as amended by EU 2023/607), are shown below:

[1] Nando (New Approach Notified and Designated Organisations) Information System, https://ec.europa.eu/growth/tools-databases/nando/.

[2] Single registration number (SRN) according to Article 31 (2) of MDR.

- 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 devices, 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)

For DNV MEDCERT GmbH

Birgit Dose
Customer Service

Appendix (see following pages):

- Table 1 and Table 2
- Revision history

Appendix

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or 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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Non-active non-implantable devices for anaesthesia, emergency and intensive care	Class Im	N/A	Certificate 1320DE416200612 NB 0482 1320GB416200612 NB 0482
Non-active non-implantable devices for anaesthesia, emergency and intensive care	Class Is	N/A	Certificate 1320DE415200612 NB 0482 1320GB415200612 NB 0482
Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools	Class Is	N/A	Certificate 1320DE415200612 NB 0482 1320GB415200612 NB 0482N/A
General non-active non-implantable devices used in health care and other non-active non implantable devices	Class Is	N/A	Certificate 1320DE415200612 NB 0482 1320GB415200612 NB 0482
Non-active non-implantable devices for anaesthesia, emergency and intensive care	Class IIa	N/A	Certificate 1320DE410200612 NB 0482 1320GB410200612 NB 0482
Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools	Class IIa	N/A	Certificate 1320DE410200612 NB 0482 1320GB410200612 NB 0482
General non-active non-implantable devices used in health care and other non-active non implantable devices	Class IIa	N/A	Certificate 1320DE410200612 NB 0482 1320GB410200612 NB 0482
Active non-implantable devices for ear, nose and throat	Class IIa	N/A	Certificate 1320DE410200612 NB 0482 1320GB410200612 NB 0482
Tracheostomy and laringectomy cannulas and kits, uncuffed	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 1320DE410200612 NB 0482 1320GB410200612 NB 0482
Tracheostomy and laringectomy cannulas and kits, cuffed	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 1320DE410200612 NB 0482 1320GB410200612 NB 0482

Tracheostomy inner cannulas	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 1320DE410200612 NB 0482 1320GB410200612 NB 0482
Phonation prostheses	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 1320DE410200612 NB 0482 1320GB410200612 NB 0482

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or 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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
None	None	None	None

Confirmation Letter Revision History:

Date	NB internal reference traceable to each version of the letter	Action
2024-09-05	1320GB454240905	Initial issue
2024-09-05	1320GB454240905	Addition of 3 EMDN codes