To whom it may concern

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Our reference: QS-0521

Notified Body Confirmation Letter
Certification No: 0521GB454231116

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.

Primed Halberstadt Medizintechnik GmbH
Straße des 20. Juli 1
38820 Halberstadt
Germany
SRN[2]: DE-MF-000004967

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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.

[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.

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:

- 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

Monika Hamann
Customer Service Manager

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
Brachytherapy radiation instruments	Class IIb implantable non-WET device	N/A	Certificate 0521GB410200424; NB 0482
Vacuum and gravity drainage systems	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 0521GB410200424; NB 0482
Glutaraldehyde for the disinfection of medical devices	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 0521GB410200424; NB 0482
Tracheostomy inner cannulas	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 0521GB410200424; NB 0482
Gastrointestinal tubes - other	Class IIa	N/A	Certificate 0521GB410200424; NB 0482
Ciaglia tracheostomy kits	Class IIa	N/A	Certificate 0521GB410200424; NB 0482
Griggs tracheostomy kits	Class IIa	N/A	Certificate 0521GB410200424; NB 0482
Tracheostomy and laringectomy cannulas and kits, uncuffed	Class IIa	N/A	Certificate 0521GB410200424; NB 0482
Tracheostomy and laringectomy cannulas - accessories	Class IIa	N/A	Certificate 0521GB410200424; NB 0482
Marking tapes, vascular structures	Class IIa	N/A	Certificate 0521GB410200424; NB 0482
Vacuum and gravity drainage systems	Class IIa	N/A	Certificate 0521GB410200424; NB 0482
Air/oxygen masks and nasal cannulas	Class IIa	N/A	Certificate 0521GB410200424; NB 0482
Intra- and postoperative blood collection and reinfusion only devices and kits	Class IIa	N/A	Certificate 0521GB410200424; NB 0482

Autologous blood collection bags	Class IIa	N/A	Certificate 0521GB410200424; NB 0482
Surgical drainage connection medical tubes	Class IIa	N/A	Certificate 0521GB410200424; NB 0482
Arthroscopy devices, single use - other	Class IIa	N/A	Certificate 0521GB410200424; NB 0482
Tracheostomy and laringectomy cannulas - accessories	Class I devices placed on the market in sterile condition	N/A	Certificate 0521GB415200424 NB 0482
Vacuum and gravity drainage systems	Class I devices placed on the market in sterile condition	N/A	Certificate 0521GB415200424 NB 0482
Surgical drainage systems - other	Class I devices placed on the market in sterile condition	N/A	Certificate 0521GB415200424 NB 0482
Tracheostomy dressings	Class I devices placed on the market in sterile condition	N/A	Certificate 0521GB415200424 NB 0482
Respiratory suction probes	Class I devices placed on the market in sterile condition	N/A	Certificate 0521GB415200424 NB 0482
Adapters and connectors	Class I devices placed on the market in sterile condition	N/A	Certificate 0521GB415200424 NB 0482
Gastrointestinal lavage, tubes and sets - other	Class I devices placed on the market in sterile condition	N/A	Certificate 0521GB415200424 NB 0482
Collection bags and other containers for drainages and fistulas, single use	Class I devices placed on the market in sterile condition	N/A	Certificate 0521GB415200424 NB 0482
Mucous aspirators	Class I devices placed on the market in sterile condition	N/A	Certificate 0521GB415200424 NB 0482
Devices for colorectal diagnostic procedures	Class I devices placed on the market in sterile condition	N/A	Certificate 0521GB415200424 NB 0482
Fluid collection bags and systems - other	Class I devices placed on the market in sterile condition	N/A	Certificate 0521GB415200424 NB 0482
Drainage and fluid collection devices - accessories	Class I devices placed on the market in sterile condition	N/A	Certificate 0521GB415200424 NB 0482

Thoracentesis and paracentesis drainages and kits	Class I devices placed on the market in sterile condition	N/A	Certificate 0521GB415200424 NB 0482
Surgical drainage connection medical tubes	Class I devices placed on the market in sterile condition	N/A	Certificate 0521GB415200424 NB 0482
Collection bags and other containers for drainages and fistulas, single use	Class I devices placed on the market in sterile condition	N/A	Certificate 0521GB415200424 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
2023-10-26	0521GB454231026	Initial issue
2023-10-30	0521GB454231030	Correction of MDD/AIMDD Certificate Reference(s) of the devices under MDR application and adding Class I devices placed on the market in sterile condition
2023-11-16	0521GB454231116	Removing 1 IIa device (C01901202) and adding 5 Class IIa devices and 2 Class I devices placed on the market in sterile condition