

To whom it may concern

DNV MEDCERT GmbH
Pilatuspool 2
20355 Hamburg
Germany

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

Date: 2023-10-30
Our reference: QS-4026

Notified Body Confirmation Letter
Certification No: 4026GB454231030

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 Nando¹, 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.

bluepoint medical GmbH & Co. KG
An der Trave 15
23923 Selmsdorf
Germany
SRN²: DE-MF-000004934

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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

Page 2 of 3

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

Lorenz Runge
Chief Certification



Appendix (see following pages):

- Table 1 and Table 2
- Revision history



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 |
|--|---|--|--|
| Pulse Oximeters | Class IIb excluding Class IIb implantable non-WET | N/A | Certificate 4026GB410210521A NB 0482 |
| Respiratory circuits supports | Class IIa | N/A | Certificate 4026GB410210521A NB 0482 |
| Pulmonary ventilators for hospital use - hardware accessories | Class IIa | N/A | Certificate 4026GB410210521A NB 0482 |
| Body temperature monitoring probes - other | Class IIa | N/A | Certificate 4026GB410210521A NB 0482 |
| Temperature monitoring cutaneous probes | Class IIa | N/A | Certificate 4026GB410210521A NB 0482 |
| Pulse oximeter sensors | Class IIa | N/A | Certificate 4026GB410210521A NB 0482 |
| Various instruments for functional exploration and therapeutic interventions - other | Class I devices with a measuring function | N/A | Certificate 4026GB416190712 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 |
|------------|---|---|
| 2023-10-27 | 4026GB454231027 | Initial issue |
| 2023-10-30 | 4026GB454231030 | Addition of Class IIa and Class I devices with a measuring function to the list |