

To whom it may concern

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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

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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

EC Certificate of Conformity

The Notified Body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany**

herewith certifies that the company:

**bluepoint medical GmbH & Co. KG
An der Trave 15
23923 Selmsdorf
Germany**

has introduced, applies and maintains a quality assurance system for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex II without section 4

This certification is subject to surveillance by MEDCERT.

Effective date: 2021-05-21

Expiry date: 2023-11-02

Report No.: 4026PS17F

Process No.: QS – 4026

Certificate No.: 4026GB410210521A

Hamburg, 2021-05-21

MEDCERT Certification Body
(Markus Bianchi)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 11 / 2019.11.14



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

Appendix of EC Certificate of Conformity

Process No.: QS – 4026

Certificate No.: 4026GB410210521A

List of products / product categories included in the scope of certificate

- Gas sampling lines
- Gas flow sensors
- Temperature probes
- SpO2 monitors
- SpO2 sensors

– End of list –

This appendix is integral part of the above-referenced certificate.
The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

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