



EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate no.
4026GB448260217

Final Assessment Report no.
4026AU22F

Effective date
2026-02-17

Expiry date
2028-11-02

This is to certify that the quality system of

bluepoint medical GmbH & Co. KG

An der Trave 15, 23923 Selmsdorf, Germany

SRN: DE-MF-000004934

For design & development, manufacturing and final product inspection/testing of
Medical devices/groups of medical devices at locations as listed on the following pages

has been assessed and found to comply with respect to

**The conformity assessment procedure described in Annex IX,
Chapters I and III of Regulation (EU) 2017/745 on Medical Devices**

Any applicable limitations for certain medical devices are included in the following list or recorded in the final assessment report. This certification is subject to surveillance by DNV MEDCERT.

Place and date
Hamburg, 2026-02-17



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
BS-MDR-096

For the issuing office
DNV MEDCERT GmbH – Notified Body 0482
Brooktorkai 18, 20457 Hamburg, Germany

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

Markus Bianchi
Certification Body Operations



Certificate no.: 4026GB448260217
Place and date: Hamburg, 2026-02-17

Sites covered by this certificate

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

Preceding certificate

Certificate no.	Issue date	Identification of changes
4026GB448240617	2024-06-17	Addition of MDA 0203 (EMDN V030102), WO-013880
4026GB448250704	2025-07-04	Addition of class IIa, MDN 1201, EMDN Z1203 according to WO-013656
4026GB448260212	2026-02-12	Change from EMDN Z1203 to Z1203010580 on customers request



Certificate no.: 4026GB448260217
Place and date: Hamburg, 2026-02-17

Products covered by this certificate

Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDA 0203	C900301	PULSE OXIMETER SENSORS
MDA 0203	V030102	BODY TEMPERATURE MONITORING PROBES
MDN 1201	Z1203010580	PULMONARY VENTILATORS FOR HOSPITAL USE - HARDWARE ACCESSORIES

Class IIb medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDA 0203	Z1203020408	PULSE OXIMETERS

Intended purpose

Pulse oximeters including accessories provide measurements of arterial blood oxygen saturation (SpO2) and pulse rate.