

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.
4026GB451230210

Final assessment report no.
4026AU19F

Effective date
2023-02-10

Expiry date
2024-11-02

This is to certify that the management system of
bluepoint medical GmbH & Co. KG
An der Trave 15, 23923 Selmsdorf, Germany

Facility ID: F006010

With the sites as mentioned on the following pages

Has been found to conform to the quality management system standard
ISO 13485:2016 and the following country-specific requirements

Australia:	Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1
Brazil:	RDC ANVISA n. 665/2022; RDC ANVISA n. 551/2021; RDC ANVISA n. 67/2009
Canada:	Medical Devices Regulations (SOR/98-282) – Part 1 (applicable requirements)
Japan:	MHLW Ministerial Ordinance 169, Article 4 to Article 68; PMD Act (as applicable)
United States:	21 CFR 803; 21 CFR 806; 21 CFR 807; 21 CFR 820

This certificate is valid for the scope of activities and products/services indicated on the following pages.

Place and date
Hamburg, 2023-02-10

DNV MEDCERT is an MDSAP
authorised auditing organisation

For the issuing office
DNV MEDCERT GmbH
Pilatuspool 2, 20355 Hamburg, Germany

Markus Bianchi
Director Certification Body

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



Certificate no.: 4026GB451230210
Place and date: Hamburg, 2023-02-10

Activities and products/services covered by this certificate

Design and development, manufacture, and distribution of

- Gas exchange monitors
- Gas sampling lines
- Flow sensors
- Temperature probes
- SpO2 modules
- SpO2 monitors
- SpO2 sensors
- Extension cables

for monitoring of vital physiological parameters

Sites covered by this certificate

bluepoint medical GmbH & Co. KG, An der Trave 15, 23923 Selmsdorf, Germany
Facility ID: F006010

Site-specific scope

Design and development, manufacture, and distribution of

- Gas exchange monitors
- Gas sampling lines
- Flow sensors
- Temperature probes
- SpO2 monitors
- SpO2 sensors
- Extension cables

for monitoring of vital physiological parameters