



DNV

# MANAGEMENT SYSTEM CERTIFICATE

Certificate no.  
2210GB451240301A

Final assessment report no.  
2210AU24F

Effective date  
2024-03-01

Expiry date  
2025-01-26

This is to certify that the management system of

**PAR Medizintechnik GmbH & Co. KG**

Rigistr. 11, 12277 Berlin, Germany

Facility ID: F006031

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  
Canada: Medical Devices Regulations (SOR/98-282) – Part 1 (applicable requirements)  
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, 2024-03-01

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

DNV MEDCERT is an MDSAP  
authorised auditing organisation

  
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 [Medcert-Info@dnv.com](mailto:Medcert-Info@dnv.com)

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

820114 EN Rev 5 2022.11.16

AUTHORISED UNIT: DNV MEDCERT GmbH (previously: MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH)  
Pilatuspool 2, 20355 Hamburg, Germany, Tel +49 40 2263325-0, [www.med-cert.com](http://www.med-cert.com), [www.dnv.com](http://www.dnv.com)



Certificate no.: 2210GB451240301A  
Place and date: Hamburg, 2024-03-01

### Activities and products/services covered by this certificate

Design and development, manufacture, final inspection, distribution and servicing of

- Monitoring devices for direct and indirect cycling measurement of vital and non vital parameters
- Modules for direct and indirect cycling measurement of vital and non vital parameters
- Related visualization software
- Cuffs for blood pressure measurement

### Sites covered by this certificate

PAR Medizintechnik GmbH & Co. KG, Rigistr. 11, 12277 Berlin, Germany  
Facility ID: F006031

Site-specific scope

Design and development, manufacture, final inspection, distribution and servicing of

- Monitoring devices for direct and indirect cycling measurement of vital and non vital parameters
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