



# MANAGEMENT SYSTEM CERTIFICATE

Certificate no.  
4153GB451240122

Final assessment report no.  
4153AU21F

Effective date  
2024-01-22

Expiry date  
2026-11-02

This is to certify that the management system of  
**DEHAS Medical Systems GmbH**

Wesloer Straße 107-109, 23568 Lübeck, Germany

Facility ID: F006011

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, 2024-01-22

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

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, www.dnv.com



Certificate no.: [4153GB451240122](#)  
Place and date: [Hamburg, 2024-01-22](#)

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

Design and development, manufacture, distribution, and servicing of

- Blenders based on oxygen mixtures, oxygen monitor and demand valves
- LOX devices for homecare

### Sites covered by this certificate

DEHAS Medical Systems GmbH, Wesloer Straße 107-109, 23568 Lübeck, Germany  
Facility ID: F006011

Site-specific scope

Design and development, manufacture, distribution, and servicing of

- Blenders based on oxygen mixtures, oxygen monitor and demand valves
- LOX devices for homecare

