



MANAGEMENT SYSTEM CERTIFICATE

Certificate no.
3189GB451230117

Final assessment report no.
3189AU23F

Effective date
2023-01-17

Expiry date
2025-04-28

This is to certify that the management system of

Human Med AG

Wilhelm-Hennemann-Straße 9, 19061 Schwerin, Germany

Facility ID: F005740

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, 2023-01-17

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 info@medcert.de

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

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

820114 EN Rev 5 2022.11.16



Certificate no.: 3189GB451230117
Place and date: Hamburg, 2023-01-17

Activities and products/services covered by this certificate

Design and development, manufacture and distribution of

- Single-use applicators for WAL devices
- WAL cannulas reusable
- Single-use WAL cannulas
- Body-jet devices for WAL
- Reusable LipoCollector devices
- Single-use LipoCollector devices
- Accessories to LipoCollector devices
- Class I medical devices/sets

Sites covered by this certificate

Human Med AG, Wilhelm-Hennemann-Straße 9, 19061 Schwerin, Germany
Facility ID: F005740

Site-specific scope

Design and development, manufacture and distribution of

- Single-use applicators for WAL devices
- WAL cannulas reusable
- Single-use WAL cannulas
- Body-jet devices for WAL
- Reusable LipoCollector devices
- Single-use LipoCollector devices
- Accessories to LipoCollector devices
- Class I medical devices/sets

Human Med AG, Wilhelm-Hennemann-Straße 20, 19061 Schwerin, Germany
Facility ID: F005740

Site-specific scope

Design and development, manufacture and distribution of

- Single-use applicators for WAL devices
- WAL cannulas reusable
- Single-use WAL cannulas
- Single-use LipoCollector devices
- Accessories to LipoCollector devices