Certificate

Certificate No.:	MD 1010032-1-1
Manufacturer:	**Löwenstein Medical Technology GmbH + Co. KG** Kronsaalsweg 40 22525 Hamburg Germany
REPs Facility ID:	F001617
Certification criteria:	ISO 13485:2016 Australia Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Brazil RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021, RDC ANVISA n. 67/2009 Canada Medical Devices Regulations – Part 1 – SOR 98/282 Japan MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D
Scope:	Design and Development, Production, Distribution and Servicing of Active Medical Devices, Patient Interfaces and Software for Diagnosis and Therapy of Respiratory Related Diseases

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.:	1125103-232
Issue Date:	2023-07-04
Effective Date:	2023-07-06
Expiry Date:	2026-07-05

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: Dipl.-Ing. S. Pane
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/9105087984?locale=en or calling 1-888-743-4652.

TUV Rheinland of North America, Inc., 295 Foster St. Suite 100, Littleton, MA 01460, USA
Tel: (925) 249-9123, Fax: (925) 249-9124

Certificate

Certificate No.: MD 1010032-1-1

Manufacturer:

Löwenstein Medical Technology GmbH + Co. KG

Kronsaalsweg 40
22525 Hamburg
Germany

The scope of certification includes the following additional sites:

No.	Location	Scope
/01	Löwenstein Medical Technology GmbH + Co. KG Südendstr. 42 76135 Karlsruhe Germany REPs ID: F004837	Design and Development of Active Medical Devices and Software for Diagnosis and Therapy of Respiratory Related Diseases

Project No.: 1125103-232

Issue Date: 2023-07-04

Effective Date: 2023-07-06

Expiry Date: 2026-07-05

MDSAP
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