

# Certificate

Certificate No.: MD 228065 3200776-90

Manufacturer: **Löwenstein Medical Technology GmbH + Co. KG**  
Kronsaalsweg 40  
22525 Hamburg  
Germany

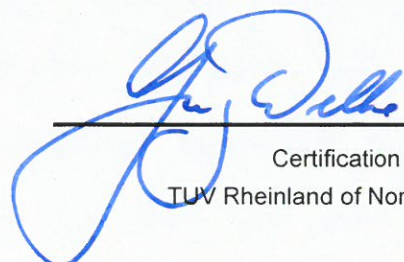
D-U-N-S No.: 31-719-8315

Certification criteria ISO 13485:2016  
Australia Therapeutic Goods (Medical Devices) Regulations, 2002,  
Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance  
Procedure  
Brazil RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC  
ANVISA n. 67/2009  
Canada Medical Devices Regulations – Part 1- SOR 98/282  
Japan MHLW Ministerial Ordinance 169, Article 4 to Article 68  
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 authorized 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 and unannounced audit(s).

Project No.: 3200776-90  
Issue Date: 2018-05-18  
Effective Date: 2018-05-18  
Expiry Date: 2020-07-05



Certification officer: J. Welte  
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified by calling 1-888-743-4652.

# Certificate

Certificate No.: MD 228065 3200776-90

Manufacturer: **Löwenstein Medical Technology GmbH + Co. KG**  
Kronsaalsweg 40  
22525 Hamburg  
Germany

Scope: The scope of Certification also includes the following additional sites:

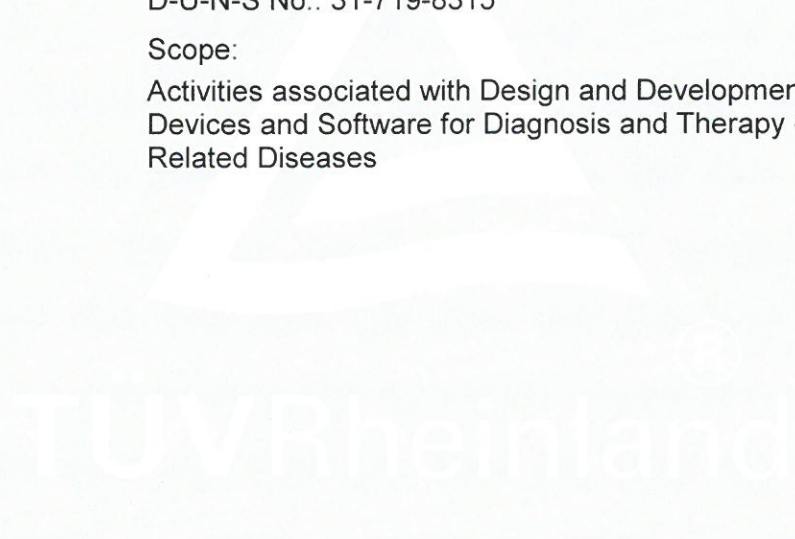
**Löwenstein Medical Technology GmbH + Co. KG**

Südenstr. 42, 76135 Karlsruhe, Germany

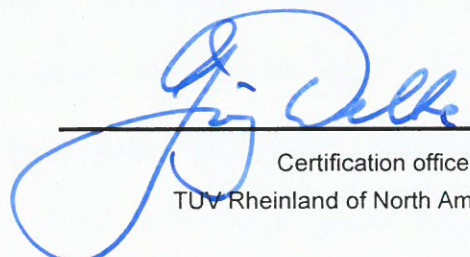
D-U-N-S No.: 31-719-8315

Scope:

Activities associated with Design and Development of Active Medical Devices and Software for Diagnosis and Therapy of Respiratory Related Diseases



Project No.: 3200776-90  
Issue Date: 2018-05-18  
Effective Date: 2018-05-18  
Expiry Date: 2020-07-05



Certification officer: J. Welte  
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified by calling 1-888-743-4652.