

Certificate

Certificate No.: MD 1011391-1-1

Manufacturer: **Löwenstein Medical SE & Co. KG**

Arzbacher Str. 80
56130 Bad Ems
Germany

REPs Facility ID: F003956

Certification criteria: ISO 13485:2016

Australia Therapeutic Goods (Medical Devices) Regulations, 2002,
Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance
Procedure

Canada Medical Devices Regulations – Part 1 – SOR 98/282

Japan MHLW Ministerial Ordinance 169, Article 4 to Article 68,
PMD Act

Scope: Design and Development, Manufacture, Distribution and Service of
anesthesia workstations and units, intensive care ventilators,
neonatology ventilators and warming units, humidifiers and tubings,
phototherapy devices for bilirubin therapy for the areas of
anesthesia, intensive care, neonatology, phototherapy, homecare,
sleep diagnostics and pulmonology

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.: 1190987-690

Issue Date: 2025-08-21

Effective Date: 2025-09-28

Expiry Date: 2028-09-27



Danide Wiedemuth

Certification officer: Dipl.-Ing. (FH) D. Wiedemuth
TUV Rheinland of North America, Inc.

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or calling 1-888-743-4652.

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The scope of certification also covers the following sites:

No.	Location	Scope
/01	Löwenstein Medical SE & Co. KG Arzbacher Str. 80 56130 Bad Ems Germany REPs Facility ID: F003956	Design and Development, Manufacture and Distribution
/02	Löwenstein Medical SE & Co. KG Arzbacher Str. 75a 56130 Bad Ems Germany REPs Facility ID: F003956	Storage
/03	Löwenstein Medical SE & Co. KG Kreuzwiese 5 56337 Simmern Germany REPs Facility ID: F003956	Manufacture and Service
/04	Löwenstein Medical SE & Co. KG Melkerstieg 20 21217 Seevetal Germany REPs Facility ID: F008369	Manufacture



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