Certificate

Certificate No.:	MD 1011391-1
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.:	1116365-100
Issue Date:	2022-12-22
Effective Date:	2022-12-22
Expiry Date:	2025-09-27

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/9105086849?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 1011391-1

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

Arzbacher Str. 80
56130 Bad Ems
Germany

The scope of certification includes the following additional sites:

No.	Location	Scope
/01	Löwenstein Medical SE & Co. KG Arzbacher Str. 80 56130 Bad Ems Germany	Design and Development, Manufacture and Distribution
/02	Löwenstein Medical SE & Co. KG Arzbacher Str. 75a 56130 Bad Ems Germany	Storage
/03	Löwenstein Medical SE & Co. KG Kreuzwiese 5 56337 Simmern Germany	Service

Project No.: 1116365-100

Issue Date: 2022-12-22

Effective Date: 2022-12-22

Expiry Date: 2025-09-27

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: Dipl.-Ing. S. Pane
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