EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III

TÜVRheinland®

Registration No.:	HZ 1010032-1
Manufacturer:	**Löwenstein Medical Technology GmbH + Co. KG** Kronsaalsweg 40 22525 Hamburg Germany
EUDAMED Single Registration No.:	DE-MF-000006010
Products:	Products of class IIa: R9099 - RESPIRATORY AND ANAESTHESIA DEVICES - OTHER R030101 - VENTILATION MASKS Products of class IIb: R9099 - RESPIRATORY AND ANAESTHESIA DEVICES - OTHER
Authorised representative(s):	N/A

Certificate history		
Revision:	Description:	Issue date:
0	Initial Certification	2020-07-13
1	New generic device group (Z121590 and R9099)	2021-07-29
2	Delete generic device group (Z121590)	2022-03-07
3	New generic device group of products class IIb (R9099)	2023-02-03

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.:	3344540-30
Effective date:	2023-02-03
Expiry date:	2025-03-10
Issue date:	2023-02-03

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
BS-MDR-091

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

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TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.