EU Certificate

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

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
Authorized representative(s):	N/A

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.:	1180098-700
Effective date:	2025-03-11
Expiry date:	2030-03-10
Issue date:	2025-03-05

Dipl.-Ing. (FH) Daniele Wiedemuth
TÜV Rheinland LGA Products GmbH
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This certificate can be validated on https://www.certipedia.com

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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Certificate history

Revision:	Description:	Issue date:
4	Re-certification. Replaces certificate HZ 1010032-1 rev. 3 issued 2023-02-03.	2025-03-05

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