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 2100418-1
Manufacturer:	**GaleMed Corporation** No. 87, Li-Gong 2nd Road, Wu-Jia, I-Lan 268 Taiwan
EUDAMED Single Registration No.:	TW-MF-000022411
Products:	Products of class I, with measuring function: Z121501 - SPIROMETRY INSTRUMENTS The scope of certification is limited to the aspects relating to the conformity of the devices with the metrological requirements Products of class IIa: R020101 - STANDARD BREATHING CIRCUITS R020102 - COAXIAL BREATHING CIRCUITS R020104 - CPAP AND NIV BREATHING CIRCUITS R020106 - IPPB CIRCUITS R030101 - VENTILATION MASKS R030102 - AIR/OXYGEN MASKS AND NASAL CANNULAS R030103 - AEROSOL THERAPY MASKS AND SYSTEMS R030202 - MANUALLY OPERATED VENTILATION BALLOONS R040102 - ANTIBACTERIAL AND ANTIVIRAL RESPIRATORY FILTERS HUMIDIFIERS R060202 - OXYGEN ADMINISTRATION HUMIDIFICATION SYSTEMS
Authorised representative(s):	Emergo Europe B.V. Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands

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.:	48220075-030
Effective date:	2023-11-13
Expiry date:	2028-05-08
Issue date:	2023-11-13

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

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No. 87, Li-Gong 2nd Road,
Wu-Jia, I-Lan 268
Taiwan

Certificate history		
Revision:	Description:	Issue date:
1	Initial Revision	2023-05-09
2	Updated address of EC-rep.	2023-11-13

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