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.
Prinsessegracht 20, 2514 AP The Hague, 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.: 238515209-065

Effective date: 2023-05-09

Expiry date: 2028-05-08

Issue date: 2023-05-09

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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

Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

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Certificate history		
Revision:	Description:	Issue date:
0	Initial Revision	2023-05-09

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