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 2058519-1

Manufacturer: **GaleMed (Xiamen) Co., Ltd.**
Xiamen Area of China (Fujian)
Pilot Free Trade Zone,
39, Section 3, Haijing East Road
361026 Fujian Province
P.R. China

EUDAMED Single Registration No.: CN-MF-000020627

Products:

Products of Class IIa:
R020101 - STANDARD BREATHING CIRCUITS
R020102 - COAXIAL BREATHING CIRCUITS
R020104 - CPAP AND NIV BREATHING CIRCUITS
R020106 - IPPB CIRCUITS
R020199 - BREATHING CIRCUITS AND KITS - OTHER
R020201 - FIXED CATHETER MOUNTS
R020202 - MOBILE CATHETER MOUNTS
R020301 - RESPIRATORY CIRCUITS CONNECTION PIPES
R020302 - RESPIRATORY CIRCUITS ADAPTERS AND CONNECTORS
R020399 - ANESTHESIA AND RESUSCITATION CONNECTORS – OTHER
R028001 - RESPIRATORY CIRCUITS VALVES
R028003 - RESPIRATORY CIRCUITS WATER TRAPS
R028099 - RESPIRATORY CIRCUITS AND MOUNT CATHETERS - ACCESSORIES NOT INCLUDED IN OTHER CLASSES
R030101 - VENTILATION MASKS
R030102 - AIR/OXYGEN MASKS AND NASAL CANNULAS
R030103 - AEROSOL THERAPY MASKS AND SYSTEMS
R030202 - MANUALLY OPERATED VENTILATION BALLOONS
R030280 - RESPIRATORY BALLONS - ACCESSORIES
R040101 - ANTIBACTERIAL AND ANTIVIRAL RESPIRATORY FILTERS

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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.: 10920489-120

Effective date: 2023-01-19

Expiry date: 2027-12-08

Issue date: 2023-01-19

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Wenxiang Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

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

DMP:2023-01-29-459662 V1.0

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

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Manufacturer:
GaleMed (Xiamen) Co., Ltd.
Xiamen Area of China (Fujian)
Pilot Free Trade Zone,
39, Section 3, Haijing East Road
361026 Fujian Province
P.R. China
R040102 - ANTIBACTERIAL AND ANTIVIRAL RESPIRATORY FILTERS HUMIDIFIERS
R040201 - TRACHEOSTOMY HUMIDIFIERS
R060280 - HUMIDIFICATION SYSTEMS - ACCESSORIES
R0680 - NEBULISATION AND HUMIDIFICATION SYSTEMS - ACCESSORIES NOT INCLUDED IN OTHER CLASSES
R9001 - RESPIRATORY MOUTHPIECES

Authorised representative(s):
EMERGO EUROPE
Prinsessegracht 20 2514 AP The Hague The Netherlands

Certificate history		
Revision:	Description:	Issue date:
0	Initial revision	2023-01-19

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