GaleMed (Xiamen) Co., Ltd.
Xiamen Area of China (Fujian) Pilot Free Trade Zone,
39, Section 3, Haijing East Road 361026 Fujian Province, China
Telephone: +86 0592 688 0588

EC Declaration of Conformity

1. MANUFACTURER	
Name of Company	GaleMed (Xiamen) Co., Ltd.
Address	Xiamen Area of China (Fujian) Pilot Free Trade Zone, 39, Section 3, Haijing East Road 361026 Fujian Province, China
SRN	CN-MF-000020627
2. AUTHORIZED REPRESENTATIVE	
Name of Company	Emergo Europe B.V.
Address	Westervoortsedijk 60, 6827 AT, Arnhem, The Netherlands
SRN	NL-AR-000000116
Email	EmergoEurope@ul.com
3. NOTIFIED BODY (NOT APPLICABLE FOR CLASS I DEVICES)	
Name of Company	TUV Rheinland LGA Products GmbH
Identification number	0197
Conformity Assessment Procedure	Annex IX, Chapter 1, section 2 and 3.
Certificate Reference(s)	HZ 2058519-1
Certificate valid period	Effective date: 2023-03-30 Expiry date: 2027-12-08
4. PRODUCT IDENTIFICATION	
Product family	Refer to attachment 1
EMDN code	Refer to attachment 1
Code / Catalog Number	Refer to attachment 1
Basic UDI-DI	Refer to attachment 1
Device Classification	Refer to attachment 1
Common Specifications/CS	N/A

OFFICIAL DOCUMENT
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This declaration of conformity is issued under the sole responsibility of GaleMed (Xiamen) Co., Ltd..

We herewith declare that the medical device(s) specified above meet the provisions of (EU) MDR 2017/745 which apply to them. This declaration is supported by the Quality Management System approval to (EU) MDR 2017/745 issued by TUV Rheinland LGA Products GmbH.

Title: Management Representative

Name: Jeann Wang

Signature: Jeann Wang

Place: Xiamen, China

Date: **2023-08-29**

此文件为盖亿(厦门)医疗器械有限公司受制文件,严禁复制 (FORM XQ4-015A v1)
CONFIDENTIAL AND PROPRIETARY INFORMATION OF GALEMED XIAMEN CO., LTD.

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Attachment 1:

No.	REF #	Other identi-fiers	Device Name	Product family	EMDN Code	Basic UDI-DI	Device Classifi-cation
1	XTF0003	41892P	NebEasy Nebulizer Kit	Disposable Aerosol therapy	R030103	69239801FD2AFKY	Class IIa
2	XTF0004	41893P	NebEasy Nebulizer Mask Adult with mask, nebulizer chamber, tubing PVC, (DEHP-free)	Disposable Aerosol therapy	R030103	69239801FD2ACKS	Class IIa
3	XTF0005	41894P	NebEasy Nebulizer Mask Child with mask, nebulizer chamber, tubing PVC, (DEHP-free)	Disposable Aerosol therapy	R030103	69239801FD2ACKS	Class IIa
4	XTF0006	1090P	Oxygen Set Adult PVC, (DEHP-free)	Disposable Oxygen therapy	R030102	69239801ND2MCPN	Class IIa
5	XTF0007	41042P	Oxygen Mask Pediatric	Disposable Oxygen therapy	R030102	69239801ND2MCPN	Class IIa
6	XTF0008	1041P	Oxygen Mask Adult	Disposable Oxygen therapy	R030102	69239801ND2MCPN	Class IIa
7	XTF0010	41098P	Fixed Venturi Mask	Disposable Oxygen therapy	R030102	69239801ND2MGPW	Class IIa
8	XTF0009	1083P	Aerosol Mask Adult PVC, (DEHP-free)	Disposable Mask	R030103	69239801ND2KAPC	Class IIa

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