Doc. No.	YM/CE 29-01	Ver.	B	Page code	1/1
Document Name	**Declaration of Conformity**	Effective Date		2021-06-01	

Manufacturer
Name：Ningbo Yingmed Medical Instruments Co.,Ltd.
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Tel.：+86-574-89065797 Fax：+86-574-89065812
European Representative:
Name： Lotus NL B.V.
Address： Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Email: peter@lotusnl.com

MEDICAL DEVICE:
Model Name: Aerosol Mask(Nebulizer Mask)
Type or size**: Adult standard, Pediatric standard, Adult elongated, Pediatric elongated**
Classification: IIa (Rule 2, Annex IX, MDD 93/42/EEC（2007）)
UMDNS code: 12449
Conformity Assessment Procedure: Annex V

We herewith declare in our own responsibility that the above-mentioned product(s) meet(s) the provisions of the Council Directive 93/42/EEC of 14th June 1993 concerning medical devices, amended by Council Directive 2007/47/EC.

General applicable directives: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning Medical devices,amended by Council Directive 2007/47/EC.
Referenced standard(s):
ISO13485:2016/ISO14971:2019/ISO11135:2014/EN980:2016/EN1041:2016/ISO11737-1:2018/ISO11737-2:2019/ISO11607-1:2019/ISO11607-2:2019/ISO10993-1:2018/ISO10993 -5:2009//ISO10993-10:2013/ISO14155:2020

Directive

Medical Device Directive: MDD 93/42/EEC
Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 MÜnchen, Germany
Notified Body Code Number: CE0123
Certificate no: G2 099261 0007 Rev. 01
Certificate period of validity:2024-05-26
Starting date to use CE logo: 2017-07-24
Signature:

Date of Issue:2021-06-01
Name: Chenyingying
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