

Doc. No.	YM/CE 30-01	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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REPUBLIC OF CHINA

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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:** Non-rebreathing mask(Oxygen mask with reservoir bag)**Type or size:** Adult standard, Pediatric standard, Adult elongated, Pediatric elongated**Classification:** IIa (Rule 2, Annex IX, MDD 93/42/EEC)**UMDNS code:** 12450**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:

陈逸超

Date of Issue:2021-06-01

Name: Chenyingying

Position: General Manage

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