

Doc. No.	YM/CE 23-01	Ver.	B	Page code	1/1
Document Name	<b>Declaration of Conformity</b>	Effective Date	2021-06-01		

**Manufacturer**

Name: Ningbo Yingmed Medical Instruments Co.,Ltd.

Address: Room 1201-9, No.456 Tai'an Middle RD, Yinzhou District,Ningbo, Zhejiang, PEOPLE'S  
REPUBLIC OF CHINA

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](mailto:peter@lotusnl.com)

**MEDICAL DEVICE:**

**Model Name:** Oxygen Masks and Oxygen Tubing

**Type or size:** Adult standard, Pediatric standard, Adult elongated, Pediatric elongated

**Classification:** IIa (Rule 2, Annex IX, MDD 93/42/EEC)

**UMDNS code:** 12448

**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:

陈逸恩

Date of Issue:2021-06-01

Name: Chenyingying

Position: General Manage

Place: Room1201-9,Yingsheng building, No.456 Tai'an RD, Southern business Zone, Yinzhou district,  
Ningbo, China

