



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

Eu representative

Name: Lotus NL B.V.

Address: Koningin Julianaplein 10, 1e
Verd, 2595AA, The Hague, Netherlands.

SRN: NL-AR-000000121

Conformity Assessment

Conformity Assessment Procedure

Annex II+III of Regulation (EU) 2017/745

Applicable Standards

EN ISO 14971: 2019

EN ISO 15223-1: 2021

EN ISO 20417: 2021

EN ISO 10993-1: 2020

EN ISO 10993-5: 2009

EN ISO 10993-10: 2023

EN ISO 10993-23: 2021

Remark

*The declaration of conformity is valid in connection
with the release technical document CE-MDR-099.*

*All the supporting documentation is retained at the
premises of the manufacturer.*

*The Declaration of Conformity is exclusively under
the sole responsibility of the manufacturer.*

Manufacturer

NAME: Ningbo Yingmed Medical Instruments
Co.,Ltd.

ADDRESS: Room 1201-9, No. 456 Tai'an middle
RD, Yinzhou District, 315199 Ningbo, Zhejiang, China

SRN: CN-MF-000002183

Product Information

Name: One Ball Spirometer

Model: YM-L4005

EMDN: V9099

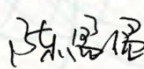
GMDN: 43017

Basic UDI-DI: 697458075L4005EQ

Classification: Class I, According to Rule 1, Annex
VIII, Regulation (EU) 2017/745

Declaration

We herewith declare that the above-mentioned
products meet the requirements of Medical Device
Regulation (EU) 2017/745 and the applicable
standards above.

Signature:  Date: 2025-6-20

Position: GM Place: Ningbo, China

宁波盈迈医疗器械有限公司
NINGBO YINGMED MEDICAL INSTRUMENTS CO., LTD