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

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

Position: GM Place: Ningbo / China