DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

CE-MDRTFA009-00,Ver.A/6

EU Representative

Lotus NL B.V.

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

SRN:NL-AR-000000121

Manufacturer

Name: Taian Dalu Medical Instrument Co., Ltd.

Address:

Factory Address 1 :No.3988 Yitianmen Street, Hi-tech Zone, Taian,271000 Shandong, P.R.China;

Factory Address 2 :No.5177 Longquan Road, Hi-tech Zone, Taian,271000 Shandong, P.R.China

SRN:CN-MF-000003009

Conformity Assessment

Conformity Assessment Procedure

Annex XI part A of Regulation (EU) 2017/745

Applicable Standards

ENISO 14971: 2019+A11:2021

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 ISO10993-12:2021

EN ISO10993-23:2021

EN ISO 13485:2016+A11:2021

EN 62366-1:2015+A1:2020

EN ISO 23747:2015

EN ISO17664-1:2021

ISO/TR 24971:2020

Remark

The declaration of conformity is valid in connection with the release technical document CE-MDRTFA009.
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.

Product Information

Name: Peak Flow Meters

Model: DL-F03, DL-F04

Basic UDI DI: 697070196460031002NG

EMDN: Z121501

Classification: Class Im, according to Rule 5, Annex VIII, Regulation (EU) 2017/745

Intended use: Measure peak expiratory flow to monitor respiratory condition

Notified Body

Name:TÜV Rheinland LGA Products GmbH

Notified Body Identification Number:

CE 0197

(EC) Certificate(s): DZ 2183264-1

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: Jin Xingmo Date:2025.07.29

Name: Jin Xingmo Place: Taian / China

Position: Management Representative