Declaration of Conformity

For the following products:

Product Name: Peak Flow Meter
Model: DL-F01, DL-F02, DL-F03, DL-F04

is hereinafter confirmed to comply with the requirements set out in the Regarding Medical Device Directive (93/42/EEC). Registration no.of EC certificate is :DD 60152549 0001

Classification:
I^{m}, Rule 5（5.1/1）, Annex IX, *Regarding Medical Device Directive (93/42/EEC).*

Notified Body:
TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Deutschland.
Notified Body number: 0197

The following representative in Europe is responsible for making this declaration:
Company Name: Lotus NL B.V.
Company Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands

The following manufacturer is responsible for making this declaration:
Company Name: Taian Dalu Medical Instrument Co., Ltd.
Company Address: West Part of Yitianmen Street, Hi-tech Zone, Taian City, Shangdong, China.

We confirm our product meets the following harmonized standards:
EN ISO 14971: 2019, EN ISO 15223-1: 2016, EN 1041: 2008, EN ISO 10993-1: 2018, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN ISO 17664:2017, EN ISO 23747:2015, EN ISO 26782:2009, ISO18562-1-2017

(Legal Signature)	General Manager (Position/title)	2021-10-13 (Date)