



# DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

## EU Representative

Lotus NL B.V.  
Koningin Julianaplein 10, 1e Verd, 2595AA,  
The Hague, Netherlands

## Conformity Assessment

### Conformity Assessment Procedure

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

### Applicable Standards

ISO 14971: 2019/EN ISO 13485:2016  
EN 1041:2008+A1:2013  
EN ISO 15223-1: 2016  
ISO 10993-1: 2018  
EN ISO 10993-5: 2009  
EN ISO 10993-10: 2013  
ISO 10993-12: 2021  
EN ISO 5356-1:2015  
EN 62366-1:2015  
ISO18562-1:2017

### Remark

*The declaration of conformity is valid in connection with the release technical document [CE-TFA005](#).*

*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: Taian Dalu Medical Instrument Co., Ltd.

Address: West Part of Yitianmen Street, Hi-tech Zone , Taian City, Shandong, China  
SRN:NL-AR-000000121



## Product Information

Name : Spacer for Aerosol

Model : See Appendix

GMDN : 38018

Basic UDI-DI : 697070196420011105KR

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:2021.05.26

Name: Wu Yu'e

Place: Taian / China

Position: MR

## Annex

Product Name	Model	GMDN	Basic UDI-DI
Spacer for Aerosol	DL-01、DL-01A、DL-01B、DL-01C、DL-01D、DL-02、DL-02A、DL-02B、DL-03、DL-03A、DL-03B、DL-03C、DL-04、DL-05、DL-06、DL-06A、DL-06B、DL-06C、DL-07、DL-08、DL-08A、DL-08B、DL-08C、DL-08D、DL-09、DL-10、DL-11、DL-12、DL-13、DL-14、DL-15、DL-16、DL-17、DL-18、DL-19、DL-20、La petite、La grande、Turbo、Aeroget、Maclife、Salbomatic、Intec、Aeromate Plus、Aerospacer Plus、aeolos、Esencia、Soldist、Farmasol	38018	697070196 420011105 KR

Signature: 

Date: 2021.05.26

Position: MR

Place: Taian City