



# DECLARATION OF CONFORMITY

ACCORDING TO Medical Device Directive 93/42/EEC

CE-TFA005-01 Ver.A/1

## EU Representative

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

## Conformity Assessment

**Conformity Assessment Procedure**  
Directive 93/42/EEC Annex V

### Applicable Standards

ISO 14971: 2019/EN ISO 13485:2016  
EN 1041:2008+A1:2013  
EN ISO 15223-1: 2016  
ENISO 10993-1: 2009+ENISO 10993-1:  
2009/ac: 2010  
EN ISO 10993-5: 2009  
EN ISO 10993-10: 2013  
EN ISO 10993-13: 2010  
EN 62366-1:2015  
EN ISO 10993-18: 2009

### 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 Yitanmen Street, Hi-tech Zone, Taian City, Shandong, China

## Product Information

**Name:** Spacer for Aerosol  
**Model:** See Appendix  
**GMDN:** 38018  
**Classification:** Class I, according to Rule 1, Annex IX, Regarding Medical Device Directive (93/42/EEC)

## Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Directive 93/42/EEC and the applicable standards above.

Signature:

Wu Yu'e

Date:2020.07.16

Name: Wu Yu'e

Place: Taian / China

Position: MR



## Annex

Product Name	Model
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

Signature:

Wu yue

Date: 2020.07.16

Position: MR

Place: Taian City

