



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

CE-MDRTFA005-00,Ver.A/2

Manufacturer

EU Representative

Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA,
The Hague, Netherlands
SRN:NL-AR-000000121

Name: Taian Dalu Medical Instrument Co., Ltd.

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

SRN:CN-MF-000003009

Product Information

Name : Spacer for Aerosol

Model : See Appendix

EMDN: R030103

Classification: Class IIa, according to Rule 2, Annex
VIII, Regulation (EU) 2017/745

Conformity Assessment

Conformity Assessment Procedure

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

Applicable Standards

ISO 14971: 2019
EN ISO13485:2016+AC:2018
ISO 20417:2021
EN ISO 15223-1: 2021
ENISO 10993-1: 2020
ISO 10993-12: 2021
EN ISO 10993-5: 2009
ISO 10993-10: 2021
ISO10993-23:2021
EN 62366-1:2015+A1:2020
ISO 17664-1:2021
ENISO18562-1:2020

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: 2023.03.02

Name: Wu Yu'e

Place: Taian / China

Position: MR

Remark

*The declaration of conformity is valid in connection
with the release technical document CE-
MDRTFA005.*

*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.*

Annex

Group	Model	Basic UDI DI
1.	DL-06C	697070196420061001M3
2.	DL-06	
3.	DL-06A	
4.	DL-06B	697070196420161002MJ
5.	DL-01D	697070196420171004MZ
6.	DL-01	
7.	DL-01A	
8.	DL-01B	
9.	DL-01C	
10.	DL-07	
11.	DL-08	
12.	DL-08A	
13.	DL-08B	
14.	DL-08C	
15.	DL-08D	
16.	DL-09	
17.	DL-10	
18.	DL-13	
19.	DL-16	
20.	DL-17	
21.	DL-18	
22.	DL-19	
23.	AS175	
24.	Intec	
25.	aeolos	
26.	Maclife	
27.	Esencia	
28.	Aeroget	
29.	Farmasol	
30.	Salbomatic	
31.	Instaspacer	
32.	Easychamber	
33.	Transpacer G	
34.	Transpacer VM	
35.	Universal-Chamber	

36.	DL-03C	697070196420191012NN
37.	DL-03	
38.	DL-03A	
39.	DL-03B	
40.	DL-14	
41.	DL-15	
42.	DL-20	
43.	Soldist	
44.	Aeromate Plus	
45.	DL-12	697070196420291003P2
46.	Turbo	697070196420091006NE
47.	La petite	
48.	DL-02	697070196420021044L9
49.	DL-02A	
50.	DL-02B	
51.	Aerospacer Plus	
52.	DL-04	697070196420041003LH
53.	DL-11	
54.	La grande	697070196420111003KV
55.	DL-05	697070196420121012L9

Signature: 

Position: MR



Date: 2023.03.02

Place: Taian City