



EU DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

CE-MDR TFA005-00, Ver.A/9

EU Representative

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

Conformity Assessment

Conformity Assessment Procedure

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

Applicable Standards

EN ISO 14971: 2019+A11:2021
EN ISO 13485:2016+AC:2018+A11:2021
EN ISO 20417:2021
ISO 15223-1:2021/Amd 1:2025
EN ISO 10993-1: 2020
EN ISO 10993-12: 2021
EN ISO 10993-5: 2009
EN ISO 10993-10: 2023
EN ISO 10993-23:2021
EN 62366-1:2015+A1:2020
EN ISO 17664-1:2021
EN ISO 18562-1:2024

Remark

The declaration of conformity is valid in connection with the release technical document **CE-MDR 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: No.3988 Yitianmen Street, Hi-tech Zone,
Taian,271000 Shandong, P.R.China
SRN:CN-MF-000003009

Product Information

Name: Spacer for Aerosol
Model : See Appendix
EMDN : R030103 - AEROSOL THERAPY MASKS AND SYSTEMS
Classification: Class IIa, according to Rule 2, Annex VIII, Regulation (EU) 2017/745
Intended use: Spacer for aerosol is intended for use by treating chronic obstructive pulmonary disease and asthma with medicine-assisted inhalation device.
The Spacer for aerosol is a holding chamber, and is used in conjunction with medication sprays or "metered dose inhalers" in the treatment of diseases of the airways.

Notified Body Name: TÜV Rheinland LGA Products GmbH

Notified Body Identification Number:



(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:  Date: 2025.07.24
Name: Jin Xingmo Place: Taian / China
Position: Management Representative



Annex

Group	Model	Basic UDI DI	Specification
1.	DL-06C	697070196420061001M3	PP-N-01
2.	DL-06		PP-N-01
3.	DL-06A		PP-N-01/02
4.	DL-06B	697070196420161002MJ	PP-I02/C02/L02/N-01
5.	DL-01D	697070196420171004MZ	ABS-I01/C01/Y01/L01/N-01/02/03
6.	DL-01		PP-I01/C01/Y01/L01/N-01/03 PETG-I01/C01/Y01/L01/N-01/03 ABS-I01/C01/Y01/L01/N-01/03 PP-I02/C02/L02/N-02 PETG-I02/C02/L02/N-02 ABS-I02/C02/L02/N-02
7.	DL-01A		PP-I01/C01/Y01/L01/N-01/02 PETG-I01/C01/Y01/L01/N-01 ABS-I01/C01/Y01/L01/N-01
8.	DL-01B		PETG-I01/C01/Y01/L01/N-01 ABS-I01/C01/Y01/L01/N-01
9.	DL-01C		PP-I02/C02/ L02/N-01 PETG-I02/C02/ L02/N-01 ABS-I02/C02/ L02/N-01
10.	DL-07		PETG-I01/C01/Y01/L01/N-01 ABS-I01/C01/Y01/L01/N-01
11.	DL-08		PP-I01/C01/Y01/L01/N-01/02 PETG-I01/C01/Y01/L01/N-01/02 ABS-I01/C01/Y01/L01/N-01/02
12.	DL-08A		PP-I01/C01/Y01/L01/N-01/02 PETG-I01/C01/Y01/L01/N-01/02 ABS-I01/C01/Y01/L01/N-01/02
13.	DL-08B		ABS-I01/C01/Y01/L01/N-01
14.	DL-08C		PP-I01/C01/Y01/L01/N-01 PETG-I01/C01/Y01/L01/N-01 ABS-I01/C01/Y01/L01/N-01
15.	DL-08D		ABS-I01/C01/Y01/L01/N-01
16.	DL-09		PETG-I01/C01/Y01/L01/N-01
17.	DL-10		PP-I02/C02/L02/N-01
18.	DL-13		ABS-I01/C01/Y01/L01/N-01/02/03
19.	DL-16		PETG-I01/C01/Y01/L01/N-01 ABS-I01/C01/Y01/L01/N-01
20.	DL-17		ABS-I01/C01/Y01/L01/N-01 PP-I01/C01/Y01/L01/N-01
21.	DL-18		PETG-I01/C01/L01-01 ABS-I01/C01/L01-01
22.	DL-19		PETG-I01/C01/Y01/L01/N-01 ABS-I01/C01/Y01/L01/N-01
23.	DL-24		ABS-D02/CC02/H02-01
24.	DL-26		ABS-D02/CC02/H02-01
25.	DL-28	PP-D02/CC02/H02-01	
26.	AS175	PETG-I01/C01/Y01/L01/N-01 ABS-I01/C01/Y01/L01/N-01	
27.	Intec	PP-I01/C01/Y01/L01/N-01/02 PETG-I01/C01/Y01/L01/N-01/02 ABS-I01/C01/Y01/L01/N-01/02	
28.	aeolos	PETG-I01/C01/Y01/L01/N-01 ABS-I01/C01/Y01/L01/N-01	
29.	Maclife	PETG-I01/C01/Y01/L01/N-01 ABS-I01/C01/Y01/L01/N-01	
30.	Esencia	PP-I01/C01/Y01/L01/N-01/02 PETG-I01/C01/Y01/L01/N-01 ABS-I01/C01/Y01/L01/N-01	
31.	Aeroget	PP-I01/C01/Y01/L01/N-01/02 PETG-I01/C01/Y01/L01/N-01/02 ABS-I01/C01/Y01/L01/N-01/02	
32.	Farmasol	PP-I01/C01/Y01/L01/N-01/02 PETG-I01/C01/Y01/L01/N-01 ABS-I01/C01/Y01/L01/N-01	
33.	Salbomatic	PP-I01/C01/Y01/L01/N-01/02	

			PETG-I01/C01/Y01/L01/N-01/02 ABS-I01/C01/Y01/L01/N-01/02	
34.	Instaspacer		ABS-I01/C01/Y01/L01/N-01/02/03	
35.	Easychamber		ABS-I01/C01/Y01/L01/N-01/02/03	
36.	Transpacer G		ABS-I01/C01/Y01/L01/N-01	
37.	Transpacer VM		ABS-I01/C01/Y01/L01/N-01	
38.	Universal-Chamber		ABS-I01/C01/Y01/L01/N-01/02/03	
39.	DL-03C	697070196420191012NN	PETG-I01/C01/Y01/L01/N-01 ABS-I01/C01/Y01/L01/N-01 PP-I01/C01/Y01/L01/N-02	
40.	DL-03		PP-I01/C01/Y01/L01/N-01 PETG-I01/C01/Y01/L01/N-01 ABS-I01/C01/Y01/L01/N-01	
41.	DL-03A		PP-I01/C01/Y01/L01/N-01 PETG-I01/C01/Y01/L01/N-01 ABS-I01/C01/Y01/L01/N-01	
42.	DL-03B		PETG-I01/C01/Y01/L01/N-01 ABS-I01/C01/Y01/L01/N-01	
43.	DL-14		PETG-I01/C01/L01-01 ABS-I01/C01/L01-01	
44.	DL-15		PP-I01/C01/Y01/L01/N-01	
45.	DL-20		PP-I01/C01/Y01/L01/N-01 PETG-I01/C01/Y01/L01/N-01 ABS-I01/C01/Y01/L01/N-01	
46.	DL-25		PETG-D02/CC02/H02-01 ABS-D02/CC02/H02-01 PP-D02/CC02/H02-01	
47.	Soldist		PP-I01/C01/Y01/L01/N-01 PETG-I01/C01/Y01/L01/N-01 ABS-I01/C01/Y01/L01/N-01	
48.	Aeromate Plus		PP-I01/C01/Y01/L01/N-01 PETG-I01/C01/Y01/L01/N-01 ABS-I01/C01/Y01/L01/N-01	
49.	DL-12		697070196420291003P2	PETG-I01/C01/Y01/L01/N-01/02 ABS-I01/C01/Y01/L01/N-01/02
50.	DL-27			PETG-D02/CC02/H02-01/02 ABS-D02/CC02/H02-01/02
51.	Turbo		697070196420091006NE	PP-I02/C02/L02/N-01
52.	La petite	PP-I02/C02/L02/N-01/02		
53.	DL-22	PP-I01/C01/Y01/L01/N-01		
54.	DL-02	697070196420021044L9	PETG-I01/C01/Y01/L01/N-01 ABS-I01/C01/Y01/L01/N-01	
55.	DL-02A		PETG-I01/C01/Y01/L01/N-01 ABS-I01/C01/Y01/L01/N-01	
56.	DL-02B		PETG-I01/C01/Y01/L01/N-01 ABS-I01/C01/Y01/L01/N-01	
57.	DL-29		PETG-D02/CC02/H02-01/02 ABS-D02/CC02/H02-01/02	
58.	Aerospacer Plus		PETG-I01/C01/Y01/L01/N-01 ABS-I01/C01/Y01/L01/N-01	
59.	DL-04	697070196420041003LH	PC-I01/C01/Y01/L01/N-01 PETG-I01/C01/Y01/L01/N-01	
60.	DL-11		ABS-I02/C02/L02/N-01	
61.	La grande	697070196420111003KV	PP-I02/C02/L02/N-01	
62.	DL-23		PP-I01/C01/Y01/L01/N-01	
63.	DL-05	697070196420121012L9	PP-I02/C02/L02/N-01	
64.	DL-21	697070196420121013LB	PP-I02/C02/L02/N-01	

Signature: *Jin Xingmo* Date: 2025.07.24

Position: Management Representative Place: Taian

