EU Certificate

Production Quality Assurance
REGULATION (EU) 2017/745 on Medical Devices
Annex XI Part A

Registration No.:	DZ 2183264-1
Manufacturer:	Taian Dalu Medical Instrument Co., Ltd. No.3988 Yitianmen Street, Hi-tech Zone, Taian, 271000 Shandong P.R. China
EUDAMED Single Registration No.:	CN-MF-000003009
Products:	Product of class IIa R030103 - AEROSOL THERAPY MASKS AND SYSTEMS Products of class I, with measuring function: Z121501- SPIROMETRY INSTRUMENTS The scope of certification is limited to the aspects relating to the conformity of the devices with the metrological requirements
Authorized representative(s):	Lotus NL B.V. Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2023-04-21
1	Products extension	2025-02-28

The Notified Body hereby declares that the requirements of Annex XI, Part A of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a production quality assurance, which is subject to periodic surveillance, defined by Annex XI, Part A, Section 7 of the aforementioned regulation.
If class III devices or class IIb devices are covered by this certificate, an EU type-examination certificate in accordance with Annex X of the aforementioned regulation is required before placing them on the market.

Report No.:	190148890-110
Effective date:	2025-02-28
Expiry date:	2028-04-20
Issue date:	2025-02-28

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This certificate can be validated on https://www.certipedia.com

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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