

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

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

Wenxiang Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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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