

Certificate

Quality Management System
EN ISO 13485:2016
EN ISO 13485:2016/AC:2018
EN ISO 13485:2016/A11:2021

Registration No.: SX 2183264-1

Certificate Holder: Taian Dalu Medical Instrument Co., Ltd.
No.3988 Yitianmen Street, Hi-tech Zone,
Taian,
271000 Shandong
P.R. China

Scope: Design and Development, Manufacture and Distribution of Disposable Oxygen Masks, Disposable Nebulizers, Face Masks, Dry Powder Inhalers, Spacer for Aerosol, Metered Dose Inhalers Actuators, Peak Flow Meters, Ultrasonic Nebulizers, Nasal Aspirator, Medical Mouthpieces, Compressor Nebulizers, Nose clips, Ocean Sea Water Nasal Spray, Electronic Actuator for Metered Dose Inhalers, Pulmonary function filters, Spirometers and Electronic Peak Flow Meters

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 190156469-110

Effective date: 2024-10-22

Expiry date: 2027-10-21

Issue date: 2024-10-18

Replaces certificate SX 2183264-1 issued 2024-09-25



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

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The scope of certification also covers the following sites:

| No. | Facility | Scope |
|-----|---|---|
| /01 | c/o Taian Dalu Medical Instrument Co., Ltd. No.3988 Yitianmen Street, Hi-tech Zone, Taian, 271000 Shandong P.R. China | Design and Development, Manufacture and Distribution of Disposable Oxygen Masks, Disposable Nebulizers, Face Masks, Dry Powder Inhalers, Spacer for Aerosol, Metered Dose Inhalers Actuators, Peak Flow Meters, Ultrasonic Nebulizers, Nasal Aspirator, Medical Mouthpieces, Compressor Nebulizers, Nose clips, Ocean Sea Water Nasal Spray, Electronic Actuator for Metered Dose Inhalers, Pulmonary function filters, Spirometers and Electronic Peak Flow Meters |
| /02 | c/o Taian Dalu Medical Instrument Co., Ltd. No.5177 Longquan Road, Hi-tech Zone, Taian 271000 Shandong P.R. China | Design and Development, Manufacture and Distribution of Face Masks, Dry Powder Inhalers, Spacer for Aerosol, Metered Dose Inhalers Actuators, Peak Flow Meters, Medical Mouthpieces, Nose clips, Pulmonary function filters and Electronic Peak Flow Meters |

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