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 Aspirators, Medical Mouthpieces, Compressor Nebulizers, Nose clips, Seawater Nasal Spray, Electronic Actuator for Metered Dose Inhalers, Pulmonary function filters, Spirometers, Electronic Peak Flow Meters, Nebulizer kits and Mobile PEF(APP)

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.:	190166737-110
Effective date:	2025-08-28
Expiry date:	2027-10-21
Issue date:	2025-08-28

Replaces certificate SX 2183264-1 issued 2025-02-27

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

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DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

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No.3988 Yitianmen Street, Hi-tech Zone,
Taian,
271000 Shandong
P.R. China

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 Aspirators, Medical Mouthpieces, Compressor Nebulizers, Nose clips, Seawater Nasal Spray, Electronic Actuator for Metered Dose Inhalers, Pulmonary function filters, Spirometers, Electronic Peak Flow Meters, Nebulizer kits and Mobile PEF(APP)
/02	c/o Taian Dalu Medical Instrument Co., Ltd. No.5177 Longquan Road, Hi-tech Zone, Taian 271000 Shandong P.R. China	Manufacture 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, Nebulizer kits and Mobile PEF(APP)

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