TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60152549 0001

Report No.: 16805094 008

Manufacturer:

Taian Dalu Medical Instrument
Co., Ltd.
West Part of Yitianmen Street
Hi-tech Zone
Taian
271000 Shandong
P.R. China

Products: Medical Devices

(See attachment for Products included)

Replaces Approval, Registration No.: DD 60145015 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2020-10-19

Date: 2020-10-19

Notified Body
TÜV Rheinland LGA Products GmbH
Zertifizierungsstelle

Wenxiang Zhang

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc 1/1, Rev 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60152549 0001
Report No.: 16805094 008

Manufacturer:
Taian Dalu Medical Instrument Co., Ltd.
West Part of Yitianmen Street
Hi-tech Zone
Taian
271000 Shandong
P.R. China

Products:

- Disposable Oxygen Masks
- Disposable Nebulizers
- Ultrasonic Nebulizers

Aspects of Manufacture Concerned with Conformity of Products with the Metrological Requirements:
- Peak Flow Meters

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Wenxiang Zhang

Date: 2020-10-19