EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 2006458-1

Manufacturer: Shenyang RMS Medical Tech Co., Ltd.
No. 10-4, Jinhui Street, Hunnan District, Shenyang City,
110179 Liaoning, P.R. China

Products: Sleep Apnoea Breathing Therapy Systems, Medical Oxygen Concentrators, Full-face Masks, Nasal Masks, Breathing Tubes, High-flow Heated Respiratory Humidifiers, Nasal Oxygen Cannulas, Heated Breathing Circuits

Replaces Approval, Registration No.: HD 60144038 0001

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.: 190131554 110

Effective date: 2021-05-06

Expiry date: 2024-05-26

Issue date: 2021-05-08

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

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

TÜVRheinland®

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2006458-1

Organization: Shenyang RMS Medical Tech Co., Ltd.
No. 10-4, Jinhui Street, Hunnan District, Shenyang City,
110179 Liaoning, P.R. China

Scope: Design and Development, Manufactuer and Distribution of Sleep Apnoea Breathing Therapy Systems, Medical Oxygen Concentrators, Full-face Masks, Nasal Masks, Breathing Tubes, High-flow Heated Respiratory Humidifiers, Nasal Oxygen Cannulas and Heated Breathing Circuits

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.: 190131554 110
Effective date: 2021-05-06
Expiry date: 2023-12-04
Issue date: 2021-05-08

TÜV Rheinland LGA Products GmbH

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