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TÜVRheinland®

EC Certificate

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

Registration No.: HD 60150327 0001

Report No.: 17058047 008

Manufacturer:
SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD.
F10-11& Sect C, F12 of BLDG 1A and F1-5 of BLDG 2 , FIYTA Timepiece Building, Nanhuan Avenue, Matian Subdistrict, Guangming District
518106 Shenzhen, Guangdong
P.R. China

Products:
Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60144776 0001

Expiry Date: 2024-05-26

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.

Effective Date: 2020-08-03

Date: 2020-08-03

Notified Body

Dipl.-Ing. W. Hsu

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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.: HD 60150327 0001
Report No.: 17058047 008

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Products:

- Anaesthetic Systems
- Syringe Pumps
- Infusion Workstation
- Infusion Pumps
- Neonatal Ventilators
- Medical Oxygen-air Blenders
- Infant Incubators
- Defibrillator/Monitors

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Dipl.-Ing. W. Hsu

Date: 2020-08-03