EC Certificate

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

Registration No.: HD 60124845 0001

Report No.: 17058047 002

Manufacturer:
SHENZHEN COMEN MEDICAL
INSTRUMENTS CO., LTD.
South of Floor 7, Block 5
4th Industrial Area of Nanyou
Nanshan District
Shenzhen
518052 Guangdong
China

Products: Medical Devices

(see attachment for products and site included)

Replaces Approval, Registration No.: HD 60113800 0001

Expiry Date: 2021-11-15

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: 2018-02-02

Date: 2018-02-02

Notified Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland
III
Zertifizierungsstelle

S. Liu

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.

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60124845 0001
Report No.: 17058047 002

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SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD.
South of Floor 7, Block 5
4th Industrial Area of Nanyou
Nanshan District
Shenzhen
518052 Guangdong
China

Products:

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

Site included:

No.2 of FIYTA Timepiece Building, Nanhuan Avenue,
Gongming sub-district, Guangming New District,
Shenzhen, 518106, Guangdong, China

Notified Body

TÜV Rheinland LGA Products GmbH
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III
Certifizierungsstelle

S. Liu

Date: 2018-02-02