EC Certificate

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

Registration No.: HD 60113800 0001

Report No.: 17062405 001

Manufacturer:
SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD.
South of Floor 7, Block 5 &
Floor 6, Block 4, 4th Industrial
Area of Nanyou, Nanshan District,
518052 Shenzhen, Guangdong
China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60108968 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: 2016-11-16

Date: 2016-10-11

Notified Body

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 60113800 0001
Report No.: 17062405 001

Manufacturer:
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South of Floor 7, Block 5 &
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518052 Shenzhen, Guangdong
China

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 TÜVRheinland Zertifizierungsstelle

S. Liu

Date: 2016-10-11