

**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



**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.

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

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**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

**Date:** 2018-02-02

