

## Certificate

The Certification Body of TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

has established and applies a quality management system for medical devices for the following scope:

Design and Development, Manufacture and Distribution of **Medical Devices** (see attachment for products and site included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:

2018-02-02

Certificate Registration No.:

SX 60124846 0001

An audit was performed. Report No.: 17058047 002

This Certificate is valid until:

2019-11-15

Certification Body



Date 2018-02-02



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety



Doc. 1/1, Rev. 0

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

Attachment to Certificate

Registration No.:

SX 60124846 0001 17058047 002

Report No.:

Organization:

SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD. South of Floor 7, Block 5 4th Industrial Area of Nanyou

Nanshan District

Shenzhen

518052 Guangdong

China

Scope:

Products:

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

Site included:

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

Design and Development, Manufacture and Distribution of the a.m. products

**Certification Body** 



Date: 2018-02-02

