

## Certificate

The Certification Body of TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

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 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:

2020-01-03

Certificate Registration No.:

SX 60144777 0001

An audit was performed. Report No.: 17058047 006

This Certificate is valid until:

2022-11-15

Certification Body



Date 2020-01-03

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



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

Doc. 1/1, Rev. 0

Attachment to Certificate

Registration No.: Report No.:

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Organization:

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

Shenzhen

518106 Guangdong

P.R. China

Scope:

Products:

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

**Certification Body** 

DAKKS

Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date: 2020-01-03

