



Certificate CN15/30545

The management system of

## Shenzhen Comen Medical Instruments Co., LTD.

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

has been assessed and certified as meeting the requirements of

# ISO 13485:2016 EN ISO 13485:2016

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 17 October 2018 until 29 April 2021  
and remains valid subject to satisfactory surveillance audits.  
Re certification audit due before 04 February 2021  
Issue 5. Certified since 30 April 2015

Authorised by

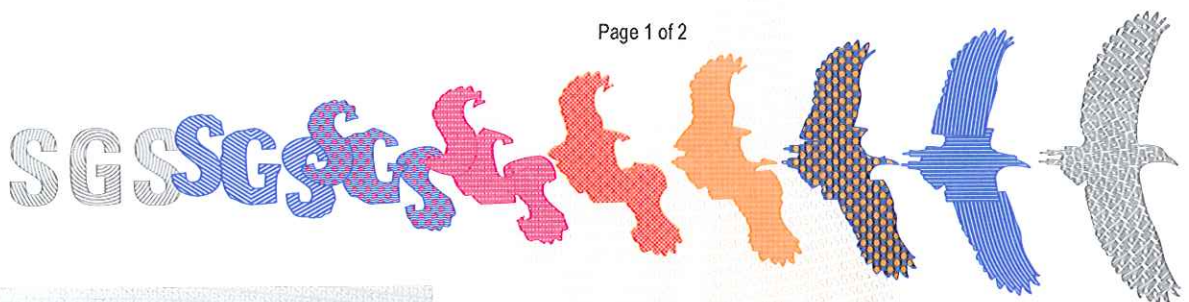
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HC SGS 13485 2016 0118 M2

Page 1 of 2



0005



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# Shenzhen Comen Medical Instruments Co., LTD.

## ISO 13485:2016 EN ISO 13485:2016



Issue 5

Detailed scope

### Design, Manufacture and Distribution of

- -Electrocardiograph,
- -Fetal & Maternal Monitor,
- -Multi-parameter Patient Monitor,
- -Specialized Cardiovascular Monitor,
  - -Vital Signs Monitor,
  - -Specialized Neonatal Monitor,
  - -Specialized Fetal/Maternal Monitor,
- -Central Monitoring System Software
  - -Infrared Ear thermometer
- -Anaesthetic Gas Scavenging System
  - -LED Surgical Light
  - -Ceiling Pendant
- -T-piece Infant Resuscitation System
  - -Anesthesia Machine,
  - -Infant Radiant Warmer.



0005