

EC Certificate Full Quality Assurance System FI21/07001

The management system of

# Shenzhen Comen Medical Instruments Co., Ltd.

Floor 10, Floor 11 and Section C of Floor 12 of Building 1A & Floor 1 to Floor 5 of  
Building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district,  
Guangming District, Shenzhen, Guangdong, 518106,  
P.R.China

has been assessed and certified as meeting the requirements of

**Directive 93/42/EEC**  
on Medical Devices, Annex II (excluding section IV)

For the following products

**High Flow Heated Respiratory Humidifiers  
Ventilators**

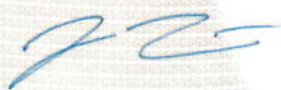
Products covered are listed in Attachment 1 of this certificate

This certificate is valid from 20 May 2021 until 24 May 2024  
and remains valid subject to satisfactory surveillance audits.

Issue 3. Certified since 20 January 2021

This certification is based on decision FI21/07055P0

Authorised by



Jani Högman  
Certifier

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## Attachment 1 to SGS Fimko Ltd. EC certificate FI21/07001, Issue 3

|                                                     |                                                                                                                                                                                                                           |
|-----------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Manufacturer</b>                                 | Shenzhen Comen Medical Instruments Co., Ltd.                                                                                                                                                                              |
| <b>Address</b>                                      | Floor 10, Floor 11 and Section C of Floor 12 of Building 1A & Floor 1 to Floor 5 of Building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R.China |
| <b>Activity and Medical Device Product Category</b> | 93/42/EEC Annex II (excluding Section 4)<br>High Flow Heated Respiratory Humidifiers<br>Ventilators                                                                                                                       |

List of medical devices and the corresponding type/model markings with product trademarks/marketing names covered by this certificate:

| <b>Medical Device</b>                   | <b>Class</b> | <b>Trademark(s) and Model(s)/type(s)</b> |
|-----------------------------------------|--------------|------------------------------------------|
| High Flow Heated Respiratory Humidifier | IIb          | NF1, NF2, NF3, NF5                       |
| Ventilator                              | IIb          | V3, V3A                                  |
| Emergency and transport ventilator      | IIb          | V1, V1A                                  |