Digitally signed by Antonova Anna
Date: 2021.08.20 14:41:16 EEST
Reason: MoldSign Signature
Location: Moldova

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

FINAS
Finnish Accreditation Service
S003 (EN ISO/IEC 17065)

This certificate is valid from 23 April 2021 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 20 January 2021
This certification is based on decision FI21/07040P0

Authorised by

Jani Högman
Certifier

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Attachment 1 to SGS Fimko Ltd. EC certificate FI21/07001, Issue 2

Manufacturer	Shenzhen Comen Medical Instruments Co., Ltd.
Address	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
Activity and Medical Device Product Category	93/42/EEC Annex II (excluding Section 4) High Flow Heated Respiratory Humidifiers Ventilators

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

Medical Device	Class	Trademark(s) and Model(s)/type(s)
High Flow Heated Respiratory Humidifier	IIb	NF1, NF2, NF3, NF5
Ventilator	IIb	V3, V3A