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, Nuanhuang 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

Products covered are listed in Attachment 1 of this certificate

This certificate is valid from 20 January 2021 until 24 May 2024 and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 20 January 2021
This certification is based on decision FI21/07004P0

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

Authorised by

Seppo Vahasalo
, Notified Body Manager

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

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, Nuanhuang 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 Humidifier

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

DECISION

21 January 2021

FI21/07004P0

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, Nuanhuang Avenue, Matian Sub-district,
Guangming District, Shenzhen, Guangdong, 518106,
P.R.China

EC-certification application 20/149-0, dated 2020-08-28

Subject	Certification of quality system and product range, based on Council Directive 93/42/EEC concerning medical devices, Annex II (excluding Section 4).
Manufacturer	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, Nuanhuang Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R.China
Decision	A certificate will be issued for the manufacturer. The certificate covers the following products:

Product	Model	Class
High flow heated respiratory humidifier	NF1, NF2, NF3, NF5	IIb

Justification	SGS Fimko Ltd has assessed manufacturer's quality management system and products. Quality management system and products meet the requirements of Annex II (excluding Section 4) of the Medical Device Directive 93/42/EEC. The decision is based on audit and technical file review reports 299996 dated 2020-09-14 and 2020-11-17. The manufacturer has signed the undertaking to follow the obligations of Annex II of the Directive 93/42/EEC.
Certificate related to decision	FI21/07001, Issue 1
Attachment to certificate	Attachment 1
Valid until	This decision is valid until 24 May.2024 providing the requirements of the certification are fulfilled.
Date	Helsinki, 20 January 2020

Seppo Vahasalo, Notified Body Manager
SGS Fimko Ltd, Notified Body 0598