EC Declaration of Conformity

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.

Whose Single Authorized Representative:
Lotus NL B.V.
Address:
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

We, the manufacturer, declare at our sole responsibility that following products

Product name	Model
High Flow Heated Respiratory Humidifier	**NF1, NF2, NF3, NF5**

UMDNS-Code: **12050**

meet the provisions of Directive 93/42/EEC.

The medical device has been assigned to class IIb according to rule 10 and rule 11 in Annex IX of the Directive 93/42/EEC. It bears the mark

CE 0598

The product concerned has been designed and manufactured under a quality management system according to Annex II (excluding Section 4) of Directive 93/42/EEC.

The product meet the following standard: (See 0230-123-02 standard list of CE conformity)

Compliance of the designated product with the Annex II (excluding Section 4) of Directive 93/42/EEC has been assessed and certified by the Notified Body

SGS FIMKO OY
Takomotie 8
00380 HELSINKI,Finland
Certificate No.: FI21/07004P0
Issue date: 2021-01-20
Expiry date: 2024-05-24

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: 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.

Shenzhen, 2021.01.22
Place, date

(Duan Gang), management Representative
Legally binding signature, Function