

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

C € 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

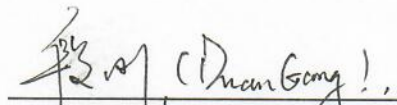
The above mentioned declaration of conformity is exclusively under the responsibility of

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Shenzhen, 2021.01.22

Place, date

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