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
Emergency and transport ventilator	**V1, V1A**

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.

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.: FI21/07001
Issue date: 2021.05.20
Expiry date: 2027.12.30

following the procedure relating to the EC Declaration of Conformity set out in Annex II of Directive 93/42/EEC.

The product meet the following standard: (See chapter 1.2 of 0212-004 product regulation and standard list)

The above mentioned declaration of conformity is exclusively under the responsibility of
Company: Shenzhen Comen Medical Instruments Co.,Ltd
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2023.7.5
Place, date

Legally binding signature, Function