

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

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2023.7.8
Place, date

段明 (Duan Ming)
Legally binding signature, Function