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
Vital Signs Monitor	NC3, NC3A, NC3B, OPUS i3, NC5A
Vital Signs Monitor	NC5

meet the provisions of Directive 93/42/EEC.

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

CE 1639

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 Belgium NV
SGS House Noorderlaan
87 2030 Antwerp Belgium
Certificate No.: CN19/41057
Issue date: 2020.01.22
Expiry date: 2023.02.05

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

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark

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

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Shenzhen 2020.2.25
Place, date

Gang Duan Management Representative
Legally binding signature, Function