EC Declaration of Conformity

Manufacturer:
Shenzhen Comen Medical Instruments Co.,Ltd
Address:
F10-11 & Sect C, F12 of BLDG 1A and F1-5 of
BLDG 2, FIYTA Timepiece Building, Nanhuan
Avenue, Matian Subdistrict, Guangming District
518106 Shenzhen Guangdong 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
Defibrillator Monitor	**S6, S8**

meet the provisions of Directive 93/42/EEC.

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

$$\text{CE } 0197$$

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

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No.: HD601447760001
Issue date: 2020-06-25
Expiry date: 2021-11-15

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

Company: Shenzhen Comen Medical Instruments Co.,Ltd
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Timepiece Building, Nanhuan Avenue, Matian Subdistrict,
Guangming District 518106 Shenzhen Guangdong P.R.China

Shenzhen , 2020.07.02
Place, date

Duanliang, Management Representative
Legally binding signature, Function