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
Defibrillator Monitor	S8, S6, S5, S3

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

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.

The product meet the following standard: (See Chapter 4 of Document No. 0039-63)

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
CertificateNo.: CN19/41057
Issuedate: 2021.03.22
Expirydate: 2023.02.05

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

Company: 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.

Shenzhen, 2021.05.08
Place, date

Gary Dunn Manager Representative
Legally binding signature, function

Digitally signed by Turcanu Stefan
Date: 2022.06.17 10:23:09 EEST
Reason: MoldSign Signature
Location: Moldova