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.

SRN: NL-AR-000000121

We, the manufacturer(SRN number: CN-MF-000002236),, declare at our sole responsibility that following products

Product name	Model	Basic UDI-DI
Defibrillator Monitor	S8, S6, S5, S3	69454290DM001K6

meet the provisions of Directive 93/42/EEC

The medical device has been assigned to class IIb according to Rule 9 and Rule 10 in Annex VIII of 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 Section4) of Directive 93/42/EEC.

Compliance of the designated product with the Annex II (excluding Section4) 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: 2028.12.31

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

The above mentioned declaration of conformity is exclusively under the responsibility of Shenzhen Comen Medical Instruments Co.,Ltd

Company: Shenzhen Comen Medical Instruments Co.,Ltd
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Digitally signed by Gobzari-Turcan Rodica
Date: 2023.06.29 10:26:06 EEST
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Location: Moldova

2023.6.16
Place, date

Legally binding signature, Function