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
Multi-parameter Patient Monitor	**STAR8000, STAR8000E, STAR8000H ,STAR8000F OPUS i12 pro**

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

Digitally signed by Antonova Anna
Date: 2021.05.26 17:53:15 EEST
Reason: MoldSign Signature
Location: Moldova

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 Appendix)

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. 2020.08.25
Place, date

Duan Gang - Management Representative
Legally binding signature, Function

Appendix

Item	Standard	
1	IEC 60601-1:2005+AMD1:2012	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
2	IEC 60601-1-2:2014	Medical electrical equipment -Part 1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic compatibility-Requirements and tests
3	ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – part 1: general requirements
4	IEC 60601-2-27:2011	Medical electrical equipment -- Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment
5	IEC 80601-2-30: 2009+ A1: 2013	Medical electrical equipment -- Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
6	IEC 60601-2-34:2011	Medical electrical equipment-Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment
7	IEC 60601-2-49:2011	Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment
8	IEC 60601-1-8:2006+AMD1:2012	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
9	ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
10	ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
11	ISO 10993-10:2010	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity
12	IEC 62304:2006+AMD1:2015	Medical device software - Software life-cycle processes
13	IEC 62366-1:2015	Medical devices – Part 1: Application of usability engineering to medical devices

14	IEC 60601-1-6:2010	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
15	ISO 80601-2-55: 2011	Medical electrical equipment -- Part 2-55 : Particular requirements for the basic safety and essential performance of respiratory gas monitors
16	ISO 80601-2-56:2009	Medical electrical equipment -- Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
17	ISO 80601-2-61:2011	Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
18	EN 1060-3: 1997+A2: 2009	Non-invasive sphygmomanometers-Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems
19	EN 1041: 2008	Information supplied by the manufacturer of medical devices