EC Declaration of Conformity

Manufacturer:
Shenzhen Comen Medical Instruments Co.,LTD
Address:
South of Floor 7, Block 5 & Floor 1 and Floor 6, Block 4, 4th Industrial Area of Nanyou,Nanshan District, Shenzhen, Guangdong 518052, P.R.China

Whose Single Authorized Representative:
Lotus Medical Equipment Limited

Address:
26B Cameron Court, Cork Street, Dublin 8, Ireland

We, the manufacturer, herewith declare that the products

Electrocardiograph
(Model:CM100, CM100A, CM300, CM300A, CM600, CM1200, CM1200A, CM1200B, H3)

meet the provisions of Directive 93/42/EEC which apply to them.

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

CE 0120

The product concerned has been designed and manufactured under a quality management system according to Annex II of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

SGS United Kingdom Limited
Unit 202B, Worle Parkway, Weston-super-Mare,
BS22 6WA, United Kingdom
Certificate No.: CN15/30546
Issue date: 30 April 2015
Expiry date: 29 April 2020

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
Address: South of Floor 7, Block 5 & Floor 1 and Floor 6, Block 4, 4th Industrial Area of Nanyou,Nanshan District, Shenzhen, Guangdong 518052, P.R.China

Shen Zhen 2016-6-17
Place, date

Legally binding signature, Function