EC Declaration of Conformity

Manufacturer:
Shenzhen Comen Medical Instruments Co.,Ltd

Address: No.2 of FIYTA Timepiece Building, Nanhuan Avenue, Gongming sub-district, Guangming New District, Shenzhen, 518106, Guangdong, China

Whose Single Authorized Representative:
Lotus NL B.V.
Address:
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

We, the manufacturer, herewith declare that the products

Product name	Model
Anesthesia Machine	*AX-400, AX-500, AX-600, AX-700*
Infusion Workstation	*M200*
Syringe Pump	*M200A*
Infusion Pump	*ME600*
Neonatal Ventilator	*NV6, NV8*
Medical Air/Oxygen Blender	*KL-20*
Neonatal Incubator	*B8, B6, B3*
Defibrillator Monitor	*S6, S8*

meet the provisions of Directive 93/42/EEC and Directive 2011/65/EU which apply to them.

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

CE 0197

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

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No.: HD601248450001
Issue date: 2018-02-02
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

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Shenzhen. 2018. 12. 03
Place, date

Legally binding signature, Function