

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.

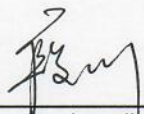
This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark

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