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,declare at our sole responsibility that following products

Product name	Model	Basic UDI-DI
Electrocardiograph	**CM300, CM300A, CM1200, CM1200A, CM1200B, H3, H12, H12A**	**69454290EL001KA**

meet the provisions of Directive 93/42/EEC.

The medical device has been assigned to class IIa according to rule 10 in Annex IX of the 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 Section 4) of Directive 93/42/EEC.

Compliance of the designated product with the Annex II (excluding Section 4) of Directive 93/42/EEChas 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: 2028.12.30

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: 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.

Shenzhen
2026.2.25
Place, date

Legally binding signature, Function

Digitally signed by Vidiborschii Vladimir
Date: 2026.05.20 10:48:42 EEST
Reason: MoldSign Signature
Location: Moldova