

## 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(SRN number: CN-MF-000002236),, declare at our sole responsibility that following products

Product name	Model	Basic UDI-DI
Electrocardiograph	CM100, CM100A, CM300, CM300A, CM600, CM1200, CM1200A, CM1200B, H3, H12, H12A	69454290EL001KA

meet the provisions of Directive 93/42/EEC

The medical device has been assigned to class IIb according to and Rule 10 in Annex VIII of 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 Section4) of Directive 93/42/EEC.

Compliance of the designated product with the Annex II (excluding Section4) of Directive 93/42/EEC has 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: 2028.12.31

The product concerned has been designed and manufactured under a quality management system according to Annex II (excluding Section4) of Directive 93/42/EEC.

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2024 7.14  
 Place, date

  
 Legally binding signature, Function