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
Vital Signs Monitor	NC3, NC3A, NC3B, OPUS i3, NC5, NC5A	69454290SM001QB

meet the provisions of Regulations (EU) 2017/745.

The medical device has been assigned to class IIb according to rule 10 in Annex VIII of MDR 2017/745. It bears the mark

CE 1639

The product concerned has been designed and manufactured under a quality management system according to Annex IX of Regulations (EU) 2017/745.

Compliance of the designated product with the Annex IX of Regulation (EU) 2017/745 has been assessed and certified by the Notified Body

SGS Belgium NV
SGS House Noorderlaan
87 2030 Antwerp Belgium
CertificateNo.: CN23/00001577
Issuedate: 2023.03.31
Expirydate: 2028.03.31

The above mentioned declaration of conformity is exclusively under the responsibility of Shenzhen Comen Medical Instruments Co.,Ltd

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.

2023.4.13
Place, date

Legally binding signature, Function