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

This declaration of conformity is issued under the sole responsibility of the manufacturer (SRN number: CN-MF-000002236). We hereby declare the medical devices specified below meet the provision of the Regulation (EU)2017/745 of the European Parliament and of the Council on medical devices.

Product name：	Specialized Fetal & Maternal Monitor
Model:	C10,C11, C20, C21, C21A, C22, C22A, C26, C29
Basic UDI-DI:	69454290FM001KU
EMDN code:	Z1203020201 BEDSIDE MULTI-PARAMETER PATIENT MONITORS
Conformity Assessment Procedure:	Annex IX excluding Chapter II.
Classification Rationale:	Class IIb per Rule 10 of Annex VIII
Standard applied:	Refer to chapter 4 of TF No.: 0161-MDR-01

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, 1639
SGS House Noorderlaan
87 2030 Antwerp Belgium
Certificate No.: CN23/00001577
Issue date: 31 March 2023
Expiry date: 31 March 2028

The CE marks

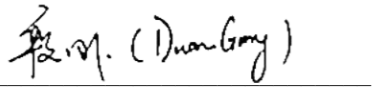
CE 1639

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.

Signed for and on behalf of: Shenzhen Comen Medical Instruments Co.,Ltd.

Duan Gang/ Representative management
(Printed Name / Position)



(Signature)

Shenzhen, China
(Place)

2024.10.31
(Date of issue)