

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:**CF5、CF5A、CF50、CF50A、CF5 R、CF5A R、CF50 R、CF50 A R、CF8、CF8A、CF80、CF80A、CF8 R、CF8A R、CF80 R、CF80 A R**Basic UDI-DI:**69454290FM002KW**EMDN code:**Z1203020201**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 No.1220-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: 04 April 2024

Expiry date: 31 March 2028

The CE marks



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)Shenzhen, China(Place)
(Signature)2024.6.21
(Date of issue)