

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:	CF3, CF3A, CF30, CF30A, CF3 R, CF3A R, CF30 R, CF30A R
Basic UDI-DI:	69454290FM003KY
EMDN code:	Z12080101
Intended purpose:	This product is intended for use in hospital to monitor the TOCO, fetal heart rate and fetal movement. This product is expected to be used in the labor and delivery room, in the prenatal examination room, and during postpartum recovery. All models of monitors shall be operated by trained health care professionals.
Conformity Assessment Procedure:	Annex IX
Classification Rationale:	Class IIb per Rule 10 of Annex VIII
Standard applied:	Refer to chapter 4 of TF No.: 1223-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

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)

Shenzhen, China
 (Place)


 (Signature)

2025.07.16
 (Date of issue)