

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
Fetal & Maternal Monitor	STAR5000, STAR5000A, STAR5000B, STAR5000C, STAR5000D, STAR5000E, STAR5000F, STAR5000H	69454290FM001KU

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

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to Floor 5 of Building 2, FIYTA Timepiece Building, Nanhuan Avenue,
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2023.7.8
Place, date


Legally binding signature, Function