

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.

We, the manufacturer, declare at our sole responsibility that following products

Product name	Model
Fetal & Maternal Monitor	STAR5000, STAR5000A, STAR5000B, STAR5000C, STAR5000D, STAR5000E, STAR5000F, STAR5000H

meet the provisions of Directive 93/42/EEC.

The medical device has been assigned to class IIb according to rule 10 in Annex IX of the Directive 93/42/EEC. It bears the mark

CE 1639

The product concerned has been designed and manufactured under a quality management system according to Annex II (excluding Section 4) of Directive 93/42/EEC.

The product meet the following standard: (See Chapter 3 of File No. 0015-64)

Compliance of the designated product with the Annex II (excluding Section 4) of Directive 93/42/EEC has been assessed and certified by the Notified Body

SGS Belgium NV**SGS House Noorderlaan****87 2030 Antwerp Belgium**

Certificate No.: CN19/41057

Issuedate: 2021.03.22

Expirydate: 2023.02.05

The above mentioned declaration of conformity is exclusively under the responsibility of

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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518106, P.R. China.

Shenzhen, 2021.05.08
Place, date

Gong Du Management Representative
Legally binding signature, Function

