

## 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
Multi-parameter Patient Monitor	C30 C30A	69454290PM001PA
	C70, C90, Datalys 770, Datalys 790, C70A, C90A	69454290PM003PE
	C50, C500, C80,C800, C86, C860,Datalys 750,Datalys 780,OPUSi15	69454290PM002PC
	NC8, NC8A, NC10, NC10A, NC12, NC12A, STAR8000A, STAR8000B, STAR8000C,OPUS i8 ,OPUS i10, OPUS i12, OPUSi10	69454290PM005PJ
	STAR8000, STAR8000E, STAR8000F, STAR8000H,OPUS i12 pro	69454290PM004PG
	K12Pro, K12APro, K15Pro, K15APro, K18Pro, K18APro, K22Pro, K22APro	69454290PM007PN
	NC19, NC19A, STAR8000D	69454290PM012PF

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  
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.

2023.4.13  
Place, date

(Dun Gay)  
Legally binding signature, Function