FOSHAN SUNTEM MEDICAL INSTRUMENT CO.,LTD

ADD: 1 Flat, No.7, C District, Sanshui Industry Park, Foshan City, GuangDong Province, China.
POSTCODE: 528137   **TEL:** +86-757-87393709   **FAX:** +86-757-87393729   E-mail: suntem@suntem.cn

EC Declaration of Conformity

Manufacturer:

Name:
Foshan Suntem Medical Instrument Co., Ltd

Address:
1 Flat, No.7, C District, Sanshui Industry Park, 528137 Foshan City, Guangdong Province, China.

whose single Authorized Representative:

Name:
Shanghai International Holding Corp. GmbH (Europe)

Address:
Eiffestrasse 80, 20537 Hamburg, Germany.
DIMDI No.: DE/0000040627

We, the manufacturer, herewith declare that the products

Product Name: EAR,NOSE&THROAT TREATMENT UNIT

Model: ST-E500, ST-E600, ST-E800, ST-E900

(Luxury patient chair,standard patient chair)

UMDNS Code: 11-585

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIa according to Annex IX of the Directive 93/42/EEC.

It bears the mark

$$C \, \epsilon \, 0197$$

The product concerned has been manufactured under a quality management system according to Annex V of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Product GmbH

Tillystraße 2 - 90431 Nürnberg, Germany

EC Certificate No.: DD 2185275-1

Effective date: 2021-01-21

Expiry date: 2024-05-26

following the procedure relating to the EC Declaration of Conformity set out in Annex VII coupled with Annex V of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark.

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

Company: Foshan Suntem Medical Instrument Co., Ltd

Address: 1 Flat, No.7, C District, Sanshui Industry Park, 528137 Foshan City, China

Foshan City 13.10.2022 .
Place , date

Legally binding signature, Function