

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: Dental Units

**Model: ST-D302, ST-D303, ST-D307, ST-D309, ST-D520, ST-D530,
ST-D540, ST-D560, ST-D570, ST-D580, ST-ANNA, ST-RYAN.**

*(motor chair, high-speed air turbine handpiece, low-speed air motor handpiece,
operating light, auto flush, 3-way syringe, cup filler system, suction,
spittoon, film viewer, foot controlled switch, curing light, scaler)*

UMDNS Code: 11-165

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



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

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

Foshan City, 30-09-2022
Place, date

