


EU Declaration of Conformity

Manufacturer:	Huizhou Foryou Medical Devices Co., Ltd.
Add.:	North Shangxia Rd., Dongjiang Hi-tech Industry Park, 516005, HuiZhou, P. R. China.
SRN:	CN-MF-000007344
Authorised Representative:	Shanghai International Holding Corp. GmbH (Europe)
Add.:	Eiffestrasse 80, 20537 Hamburg, Germany
Product Name:	Nasal Dressing
Trade Name:	SUNTOUCH®
Type/Specification:	See Annex I
Basic UDI-DI:	69406101ND001162
EMDN Code:	M040599
GMDN Code:	31919
Classification:	I, Sterile, MDD 93/42/EEC Appendix IX, Rule 5
Conformity Assessment:	Annex V of MDD 93/42/EEC
General Applicable Regulations:	COUNCIL DIRECTIVE 93/42/EEC concerning medical devices (MDD 93/42/EEC); Regulation(EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices, Article 120.
Standards Applied:	All applicable standards
Notified Body:	TÜV SÜD Product Service GmbH, Ridlerstr. 65, D-80339 München, Germany
Identification Number:	
(EC)Certificate(s):	G2S 065520 0038 Rev.00
Expire Date of the Certificate:	2024-05-26

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Regulations and Standards. All supporting documentations are retained under the premises of the manufacturer.

The manufacturer is exclusively responsible for the declaration of conformity.

Signature:

Place and Date of Issue:

Huizhou / 2023.01.03

Yang Zhang**Person Responsible for Regulatory Compliance**

Annex I

This appendix declares the products included in the above referenced Declaration of Conformity.

L&R REF code	Foryou REF code	Product size
147340	ND0551B	55×25×15mm
147341	ND1001B	100×25×15mm
147342	ND0452B	45×20×15mm
147343	ND0452T	45×20×15mm
147344	ND0802B	80×20×15mm
147345	ND0802T	80×20×15mm