



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: Medical Sponges
Trade Name: SUNTOUCH®
Type/Specification: See Annex I
Basic UDI-DI: /
EMDN Code: Eye Spear, Eye Wicks, Eye Drains, Corneal Light Shield, Medical Sponge Tips:
M040399
Ear Tampon: M0407
GMDN Code: Eye Spear, Eye Wicks, Eye Drains, Corneal Light Shield, Medical Sponge Tips:
13704
Ear Tampon: 33468
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: 2028-12-31

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:


.....

Yang Zhang
Person Responsible for Regulatory Compliance

Place and Date of Issue:

..... Huizhou / 2024.1.4

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Annex I

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

Eye Spear	
REF	Description
ES1001A	With handle, 17×10×9mm
ES1001B	No handle, 17×10×9mm
ES1002A	With handle, 17×8×9mm
ES1002B	No handle, 17×8×9mm
ES1003B	No handle, 25×8×9mm

Ear Tampon	
REF	Description
ET0915A	With string, 9×15mm
ET0915B	No string, 9×15mm
ET0924A	With string, 9×24mm
ET0924B	No string, 9×24mm
ET1215A	With string, 12×15mm
ET1215B	No string, 12×15mm
ET1224A	With string, 12×24mm
ET1224B	No string, 12×24mm
ET1520A	With string, 15×20mm
ET1520B	No string, 15×20mm
ET1522A	With string, 15×22mm
ET1522B	No string, 15×22mm
ET1524A	With string, 15×24mm
ET1524B	No string, 15×24mm

Eye Wicks	
REF	Description
EW15025	150×2.5×1.3mm
EW15011	150×1.1×1.3mm
EW17040	170×4×1.3mm
EW20030	200×3×1.3mm
B-EW17545	175×4.5×1.9mm

Eye Drains	
REF	Description
ED101A	10×14×8.5×0.75mm
ED101B	No handle, 10×14×8.5×0.75mm
ED102A	10×14×9.5×0.75mm
ED102B	No handle, 10×14×9.5×0.75mm
ED103A	10×14×8.5×2mm
ED103B	No handle, 10×14×8.5×2mm
ED104A	10×14×9.5×2mm
ED104B	No handle, 10×14×9.5×2mm
ED105A	10×14×10.5×2mm
ED105B	No handle, 10×14×10.5×2mm
ED106A	12×15×9.5×2mm
ED106B	No handle, 12×15×9.5×2mm
ED107A	12×15×10.5×2mm
ED107B	No handle, 12×15×10.5×2mm

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ED108A	12×17×11.5×2mm
ED108B	No handle,12×17×11.5×2mm
ED109A	18×14×1mm
ED109B	No handle,18×14×1mm
ED110A	14×9×1.5mm
ED110B	No handle,14×9×1.5mm

Corneal Light Shield	
REF	Description
LS700	7×2mm
LS800	8×2mm
LS900	9×2 mm
LS705	7×2×5 mm
LS806	8×2×6mm
LS907	9×2×7mm
LS884	8×2×4×8mm

Medical sponge tips	
REF	Description
BT-100	6.0 (Φ) mm×8.0 (L) mm