

The Declaration of Conformity

Manufacturer: Huizhou Foryou Medical Devices Co., Ltd.
Add. North Shangxia Rd., Dongjiang Hi-tech Industry Park,
516005, HuiZhou, P. R. China.

European Representative: Shanghai International Holding Corp.GmbH(Europe)
Add. Eiffestrasse 80, 20537 Hamburg, Germany

Products Name: PermaFoam classic, PermaFoam classic Border,
PermaFoam Sacral, PermaFoam Concave,
PermaFoam Tracheostomy

Size Specification: Listed in Annex I
GMDN Code: P46854
Classification: II b, MDD 93/42/EEC Appendix IX, Rule4
Conformity Assessment Route: Annex II .3 of MDD 93/42/EEC

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

Directives

General Applicable Directives:
Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC concerning medical devices (MDD 93/42/EEC).

Standards Applied: All applicable standards.

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65,
D-80339 München, Germany

Identification Number: CE0123
(EC)Certificate(s): G1 065520 0034 Rev. 01
Expire Date of the Certificate: 2023-07-24
Start CE Marking: 2010-03-18

Place and Date of Issue: Huizhou / 2019-09-20

Signature: 
Name: Zhang Yang
Position: Management Representative

Annex I

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

Item	Size
PermaFoam Classic (non-border)	10cm×10cm
	15cm x 15cm
	20cm×10cm
	20cm×20cm
	6cm round
PermaFoam Classic Border	10cm×10cm
	15cm x 15cm
	30cm×10cm
PermaFoam Classic Sacral	18cm x 18 cm
	22.5cm x 22.5 cm
PermaFoam Classic Concave	16.5cm x 18 cm
PermaFoam Classic Tracheostomy (non-border)	8cm x 8 cm

Signature: 张杨

Name: Zhang Yang

Position: Management Representative