

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
SRN of Authorised Representative: DE-AR-000000001
Product Name: PermaFoam® Classic , PermaFoam® Classic Round, PermaFoam® Classic Tracheostomy, PermaFoam® Classic Border, PermaFoam® Classic Sacral, PermaFoam® Classic Concave
Trade Name: PermaFoam®
Type/Specification: See Annex I
Basic UDI-DI: Non Border: 69406101FD00012P; Adhesive Island: 69406101FD00032T;
EMDN Code: M040406 POLYURETHANE DRESSINGS
GMDN Code: 44970
Classification: II b, REGULATION (EU) 2017/ 745(MDR) Annex VIII, rule 4
Conformity Assessment: REGULATION (EU) 2017/745, Annex IX Chapter I +III
General Applicable Regulations: REGULATION (EU) 2017/745 (MDR), Regulation (EC) No 1907/2006 of the European Parliament and of the Council Concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).
Standards Applied: EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 14971:2019/A11:2021, CEN ISO/TR 24971:2020, EN ISO 4180:2019, ISTA 3A: 2018, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 14644-1:2015, EN ISO 10993-1:2020, EN ISO 10993-3:2014, EN ISO 10993-5:2009, EN ISO 10993-6:2016, EN ISO 10993-7:2008, EN ISO 10993-7:2008/AC:2009, ISO 10993-10:2021, EN ISO 10993-11:2018, EN ISO 10993-12:2021, EN ISO 11135:2014, EN ISO 11135:2014/A1:2019, EN ISO 11138-1:2017, EN ISO 11138-2:2017, EN ISO 11140-1:2014, EN ISO 15223-1:2021, EN ISO 20417:2021, EN ISO 11737-1:2018, EN ISO 11737-1:2018/A1:2021, EN ISO 11737-2:2020, ASTM F 1980:2021, EN ISO 14155:2020, MDCG 2020-10/1, MEDDEV. 2.7.1 Rev.4, MEDDEV. 2.12-2 Rev.2, MDCG 2020-5, MDCG 2020-6, MDCG 2020-7, MDCG 2020-8, MDCG 2020-13, MEDDEV 2.12-1 rev 8, EN 13726-1:2002, EN 13726-1:2002/AC:2003, EN 13726-2:2002, EN 13726-3:2003, EN 13726-4:2003, EN 62366-1:2015, EN ISO 10993-23:2021.
Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65, D-80339 München, Germany
Identification Number: 
(EC)Certificate(s): G10 065520 0040 Rev. 01
Expire Date of the Certificate: 2027-09-04

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:



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Yang Zhang

Person Responsible for Regulatory Compliance

Place and Date of Issue:

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Huizhou 2024-10-23

Annex I

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

REF #	Product Description	Brand Name
882100	PermaFoam Classic(non-border) 6cm Round P10	PermaFoam® Classic Round
882101	PermaFoam Classic(non-border)10cm×10cm P10	PermaFoam® Classic
882102	PermaFoam Classic(non-border)15cm×15cm P10	PermaFoam® Classic
882103	PermaFoam Classic(non-border) 10cm×20cm P10	PermaFoam® Classic
882104	PermaFoam Classic(non-border) 20cm×20cm P10	PermaFoam® Classic
882105	PermaFoam Classic Tracheostomy (non-border) 8cm×8cm P10	PermaFoam® Classic Tracheostomy
882106	PermaFoam Classic Border 10cm×10cm P10	PermaFoam® Classic Border
882107	PermaFoam Classic Concave 16.5cm×18cm P10	PermaFoam® Classic Concave
882108	PermaFoam Classic Border 15cm×15cm P10	PermaFoam® Classic Border
882109	PermaFoam Classic Border 10cm×30cm P10	PermaFoam® Classic Border
882110	PermaFoam Classic Sacral 18cm×18cm P10	PermaFoam® Classic Sacral
882111	PermaFoam Classic Sacral 22.5cm×22.5cm P10	PermaFoam® Classic Sacral
882104	PermaFoam Classic(non-border) 20cm×20cm P10	PermaFoam® Classic
882105	PermaFoam Classic Tracheostomy (non-border) 8cm×8cm P10	PermaFoam® Classic Tracheostomy
882106	PermaFoam Classic Border 10cm×10cm P10	PermaFoam® Classic Border

882107	PermaFoam Classic Concave 16.5cm×18cm P10	PermaFoam® Classic Concave
882108	PermaFoam Classic Border 15cm×15cm P10	PermaFoam® Classic Border
882109	PermaFoam Classic Border 10cm×30cm P10	PermaFoam® Classic Border
882110	PermaFoam Classic Sacral 18cm×18cm P10	PermaFoam® Classic Sacral
882111	PermaFoam Classic Sacral 22.5cm×22.5cm P10	PermaFoam® Classic Sacral