


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: PermaFoam® Classic, PermaFoam® Classic Border, PermaFoam® Classic Sacral, PermaFoam® Classic Concave, PermaFoam® Classic Tracheostomy
Trade Name: PermaFoam®
Type/Specification: See Annex I
Basic UDI-DI: /
EMDN Code: M040406
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:

Place and Date of Issue:

.....
Yang Zhang

..... Huizhou 2024-09-03

Person Responsible for Regulatory Compliance

Annex I

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

Product Description	Brand Name
PermaFoam Classic (non-border) 10x10cm P10	PermaFoam® Classic
PermaFoam Classic (non-border) 15x15cm P10	PermaFoam® Classic
PermaFoam Classic (non-border) 20x10cm P10	PermaFoam® Classic
PermaFoam Classic (non-border) 20x20cm P10	PermaFoam® Classic
PermaFoam Classic (non-border) 6cm round P10	PermaFoam® Classic
PermaFoam Classic Tracheostomy (non-border) 8x8cm P10	PermaFoam® Classic Tracheostomy
PermaFoam Classic Border 10x10cm P10	PermaFoam® Classic Border
PermaFoam Classic Border 15x15cm P10	PermaFoam® Classic Border
PermaFoam Classic Border 30x10cm P10	PermaFoam® Classic Border
PermaFoam Classic Concave 16.5x18cm P10	PermaFoam® Classic Concave
PermaFoam Classic Sacral 18x18cm P10	PermaFoam® Classic Sacral
PermaFoam Classic Sacral 22.5x22.5cm P10	PermaFoam® Classic Sacral