


## 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:** IIb, MDD 93/42/EEC Appendix IX, Rule 4  
**Conformity Assessment:** Annex II.3 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):** G1 065520 0034 Rev. 02  
**Expire Date of the Certificate:** 2023-7-24  
**Confirmation Letter:** CL 065520 0044 Rev. 02  
**Expire Date of the Confirmation Letter:** 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:**



**Place and Date of Issue:**

Huizhou / 2024.8.7

**Yang Zhang**

**Person Responsible for Regulatory Compliance**

**Annex I**

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

<b>REF #</b>	<b>Product Description</b>	<b>Brand Name</b>
882 000	PermaFoam Classic (non-border) 10x10cm P10	PermaFoam® Classic
882 001	PermaFoam Classic (non-border) 15x15cm P10	PermaFoam® Classic
882 002	PermaFoam Classic (non-border) 20x10cm P10	PermaFoam® Classic
882 003	PermaFoam Classic (non-border) 20x20cm P10	PermaFoam® Classic
882 004	PermaFoam Classic (non-border) 6cm round P10	PermaFoam® Classic
882 005	PermaFoam Classic Tracheostomy (non-border) 8x8cm P10	PermaFoam® Classic Tracheostomy
882 006	PermaFoam Classic Border 10x10cm P10	PermaFoam® Classic Border
882 007	PermaFoam Classic Border 15x15cm P10	PermaFoam® Classic Border
882 008	PermaFoam Classic Border 30x10cm P10	PermaFoam® Classic Border
882 009	PermaFoam Classic Concave 16.5x18cm P10	PermaFoam® Classic Concave
882 011	PermaFoam Classic Sacral 18x18cm P10	PermaFoam® Classic Sacral
882 012	PermaFoam Classic Sacral 22.5x22.5cm P10	PermaFoam® Classic Sacral