FORYOU MEDICAL

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:	Foam Dressing
Trade Name:	Suprasorb P nk®
Intended purpose:	Foam Dressing is indicated for moderately to heavily exuding wounds, such as venous leg ulcers, pressure ulcers, diabetic foot ulcers, donor sites, abrasions, and surgical wounds.
Type/Specification:	See Annex Ⅰ
Basic UDI-DI:	Non Border: 69406101FD00012P; Versatile: 69406101FD00022R; Adhesive Island: 69406101FD00032T; Comfort: 69406101FD00042V; Adhesive Island Comfort: 69406101FD00052X
EMDN Code:	M040406 POLYURETHANE DRESSINGS
GMDN Code:	44970
Classification:	Ⅱb, 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:	CE 0123
(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.

FORYOU MEDICAL

Signature:

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Yang Zhang

Person Responsible for Regulatory Compliance

Place and Date of Issue:

Huizhou 2026-02-26

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Annex I

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

L&R description	Product size (mm)	L&R REF code	Foryou REF code
Suprasorb P nk 15x20 5 ste	200x150	401179	HFD200150C
Suprasorb P nk 5x5 10ste	50x50	401180	HFD050050C
Suprasorb P nk 7,5x7,5 10ste	75x75	401181	HFD075075C
Suprasorb P nk 10x10 10ste	100x100	401182	HFD100100C
Suprasorb P nk 15x15 5ste	150x150	401183	HFD150150C
Suprasorb P nk 10x12 10ste	120x100	401184	HFD120100C
Suprasorb P nk 12,5x12,5 10ste	125x125	401185	HFD125125C
Suprasorb P nk 20x20 5ste	200x200	401186	HFD200200C
Suprasorb P nk 15x15 10ste F	150x150	401187	HFD150150C
Suprasorb P nk 15x20 10ste F	200x150	401188	HFD200150C
Suprasorb P nk 5x5 10ste F	50x50	401189	HFD050050C
Suprasorb P nk 7,5x7,5 10ste F	75x75	401190	HFD075075C
Suprasorb P nk 10x10 10ste F	100x100	401191	HFD100100C