

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: Silicone Foam Dressing
Trade Name: Suprasorb®
Type/Specification: See Annex I
Basic UDI-DI: 69406101SF00018N
EMDN Code: M040406 POLYURETHANE DRESSINGS
GMDN Code: 46854
Classification: IIb, REGULATION (EU) 2017/745 (MDR) Appendix 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, ISO 4180:2019, ASTM D 4169-16, ISTA 3A: 2018, EN ISO 11607-1:2020, EN ISO 11607-2:2020, 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, EN ISO 10993-10:2013, 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 1980:2016, EN ISO 14155:2011, MEDDEV. 2.7.1 Rev.4, MEDDEV. 2.12-2 Rev.2, MEDDEV 2.12-1 rev 8, EN 13726-1:2002, EN 13726-2:2002, EN 13726-3:2003, EN 13726-4:2003, IEC 62366-1: 2015
Notified Body: TÜV SÜD Product Service GmbH, Ridlerstraße. 65 • 80339 Munich • Germany
Identification Number: 
(EC)Certificate(s): G10 065520 0040 Rev. 00
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:

..... Huizhou / 2022.09.15

Annex I

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

Items	L&R REF	L&R description	Size	REF code
Border	109061	Suprasorb P sensitive PU foam dressing, sterile, border, 10x10cm, 10 pieces	100 x 100 (62x62) mm	HSF100100F
	109062	Suprasorb P sensitive PU foam dressing, sterile, border, 12,5x12,5cm, 10 pieces	125 x 125 (85x85) mm	HSF125125F
	109068	Suprasorb P sensitive PU foam dressing, sterile, border, 7,5x8,5cm, 10 pieces	75 x 85 (45x50) mm	HSF075085F
	109069	Suprasorb P sensitive PU foam dressing, sterile, border, 15x15cm, 10 pieces	150 x 150 (105x105) mm	HSF150150F
	109070	Suprasorb P sensitive PU foam dressing, sterile, border, 20x20cm, 10 pieces	200 x 200 (150x150) mm	HSF200200F
	140160	Suprasorb P sensitive PU foam dressing, sterile, border, 5x5cm, 10 pieces	50 x 50 (25x25)mm	HSF050050F
	140161	Suprasorb P sensitive PU foam dressing, sterile, border, 7,5x7,5cm, 10 pieces	75 x 75 (45x45)mm	HSF075075F
	139061	Suprasorb P sensitive PU foam dressing, sterile, border, 10x10cm, 10 pieces	100 x 100 (62x62) mm	HSF100100F
	139062	Suprasorb P sensitive PU foam dressing, sterile, border, 12,5x12,5cm, 10 pieces	125 x 125 (85x85) mm	HSF125125F
	139068	Suprasorb P sensitive PU foam dressing, sterile, border, 7,5x8,5cm, 10 pieces	75 x 85 (45x50) mm	HSF075085F
	139069	Suprasorb P sensitive PU foam dressing, sterile, border, 15x15cm, 10 pieces	150 x 150 (105x105) mm	HSF150150F
	140162	Suprasorb P sensitive PU foam dressing, sterile, border, 15x20cm, 10 pieces	150 x 200 (105x150) mm	HSF150200F
	139070	Suprasorb P sensitive PU foam dressing, sterile, border, 20x20cm, 10 pieces	200 x 200 (150x150) mm	HSF200200F
	140169	Suprasorb P sensitive PU foam dressing, sterile, border, 7,5x7,5cm, 3 pieces, Sample	75 x 75 (45x45) mm	HSF075075F
	140166	Suprasorb P sensitive PU foam dressing, sterile, border, 10x10cm, 3 pieces, Sample	100 x 100 (62x62) mm	HSF100100F

	146240	Suprasorb P sensitive PU foam dr,sterile border 10x30cm, 5 pcs.	300 x 100 (240x50) mm	HSF300100F
	146241	Suprasorb P sensitive PU foam dr,sterile border 10x30cm, 10 pcs.	300 x 100 (240x50) mm	HSF300100F
Border Lite	109080	Suprasorb P sensitive PU foam dressing, sterile, border lite, 5x5cm, 10 pieces	50 x 50 (25x25)mm	HSF050050L3
	109081	Suprasorb P sensitive PU foam dressing, sterile, border lite, 5x10cm, 10 pieces	50 x 100 (25x60)mm	HSF050100L3
	109083	Suprasorb P sensitive PU foam dressing, sterile, border lite, 10x10cm, 10 pieces	100 x 100 (62x62) mm	HSF100100L3
	109086	Suprasorb P sensitive PU foam dressing, sterile, border lite, 7,5x8,5cm, 10 pieces	75 x 85 (45x50) mm	HSF075085L3
	109087	Suprasorb P sensitive PU foam dressing, sterile, border lite, 9x15cm, 10 pieces	90 x 150 (50x105) mm	HSF090150L3
	109088	Suprasorb P sensitive PU foam dressing, sterile, border lite, 10x20cm, 10 pieces	100 x 200 (50x150) mm	HSF100200L3
	139080	Suprasorb P sensitive PU foam dressing, sterile, border lite, 5x5cm, 10 pieces	50 x 50 (25x25)mm	HSF050050L3
	140163	Suprasorb P sensitive PU foam dressing, sterile, border lite, 7,5x7,5cm, 10 pieces	75 x 75 (45x45)mm	HSF075075L3
	139081	Suprasorb P sensitive PU foam dressing, sterile, border lite, 5x10cm, 10 pieces	50 x 100 (25x60)mm	HSF050100L3
	139083	Suprasorb P sensitive PU foam dressing, sterile, border lite, 10x10cm, 10 pieces	100 x 100 (62x62) mm	HSF100100L3
	139086	Suprasorb P sensitive PU foam dressing, sterile, border lite, 7,5x8,5cm, 10 pieces	75 x 85 (45x50) mm	HSF075085L3
	139087	Suprasorb P sensitive PU foam dressing, sterile, border lite, 9x15cm, 10 pieces	90 x 150 (50x105)mm	HSF090150L3
	139088	Suprasorb P sensitive PU foam dressing, sterile, border lite, 10x20cm, 10 pieces	100 x 200 (50x150)mm	HSF100200L3
	140164	Suprasorb P sensitive PU foam dressing, sterile, border lite, 15x15cm, 10 pieces	150 x 150 (105x105) mm	HSF150150L3
	140165	Suprasorb P sensitive PU foam dressing, sterile, border lite, 15x20cm, 10 pieces	150 x 200 (105x150) mm	HSF150200L3
	140170	Suprasorb P sensitive PU foam dressing, sterile, border lite, 7,5x7,5cm, 3 pieces, Sample	75 x 75 (45x45) mm	HSF075075L3

	140167	Suprasorb P sensitive PU foam dressing, sterile, border lite, 10x10cm, 3 pieces, Sample	100 x 100 (62x62) mm	HSF100100L3
	146242	Suprasorb P sensitive PU foam dr,sterile border lite 6x12cm, 10 pcs.	120 x 60 (80x30) mm	HSF120060L3
	146243	Suprasorb P sensitive PU foam dr,sterile border lite 6x12cm, 10 pcs.	120 x 60 (80x30) mm	HSF120060L3
Non-Border	139590	Suprasorb P sensitive PU foam dressing, sterile, non-border, 5x5cm, 10 pieces	50 x 50 mm	HSF050050N
	139592	Suprasorb P sensitive PU foam dressing, sterile, non-border, 10x10cm, 10 pieces	100 x 100 mm	HSF100100N
	139593	Suprasorb P sensitive PU foam dressing, sterile, non-border, 10x20cm, 10 pieces	100 x 200 mm	HSF100200N
	139595	Suprasorb P sensitive PU foam dressing, sterile, non-border, 15x15cm, 10 pieces	150 x 150 mm	HSF150150N
	139597	Suprasorb P sensitive PU foam dressing, sterile, non-border, 20x20cm, 10 pieces	200 x 200 mm	HSF200200N
	139591	Suprasorb P sensitive PU foam dressing, sterile, non-border, 7,5x7,5cm, 10 pieces	75 x 75 mm	HSF075075N
	139596	Suprasorb P sensitive PU foam dressing, sterile, non-border, 15x20cm, 10 pieces	150 x 200 mm	HSF150200N
	140171	Suprasorb P sensitive PU foam dressing, sterile, non-border, 7,5x7,5cm, 3 pieces, Sample	75x75 mm	HSF075075N
	140168	Suprasorb P sensitive PU foam dressing, sterile, non-border, 10x10cm, 3 pieces, Sample	100 x 100 mm	HSF100100N
	139350	Suprasorb P sensitive PU foam dressing, sterile, non-border, 5x5cm, 10 pieces	50 x 50 mm	HSF050050N
	139351	Suprasorb P sensitive PU foam dressing, sterile, non-border, 10x10cm, 10 pieces	100 x 100 mm	HSF100100N
	139352	Suprasorb P sensitive PU foam dressing, sterile, non-border, 10x20cm, 10 pieces	100 x 200 mm	HSF100200N
	139353	Suprasorb P sensitive PU foam dressing, sterile, non-border, 15x15cm, 10 pieces	150 x 150 mm	HSF150150N
	139354	Suprasorb P sensitive PU foam dressing, sterile, non-border, 20x20cm, 10 pieces	200 x 200 mm	HSF200200N
	139455	Suprasorb P sensitive PU foam dressing, sterile, non-border, 7,5x7,5cm, 10 pieces	75 x 75 mm	HSF075075N

	139456	Suprasorb P sensitive PU foam dressing, sterile, non-border, 15x20cm, 10 pieces	150 x 200 mm	HSF150200N
	146244	Suprasorb P sensitive PU foam dr,sterile tracheo non border, 10x9cm, 10 pcs.	100 x 90mm	HSF100090NX
Sacrum	139365	Suprasorb P sensitive PU foam dressing, sterile, sacrum, 17x17,5cm, 10 pieces	170 x 175 (120x125)mm	HSF175170FS
	139556	Suprasorb P sensitive PU foam dressing, sterile, sacrum, 23x23cm, 10 pieces	230 x 230 (165x170)mm	HSF230230FS
	139355	Suprasorb P sensitive PU foam dressing, sterile, sacrum, 17x17,5cm, 10 pieces	170 x 175 (120x125)mm	HSF175170FS
	139566	Suprasorb P sensitive PU foam dressing, sterile, sacrum, 23x23cm, 10 pieces	230 x 230 (165x170)mm	HSF230230FS
Heel	139368	Suprasorb P sensitive PU foam dressing, sterile, heel, 23,5x25cm, 10 pieces	235 x 250 (175x190)mm	HSF250235FH
	139356	Suprasorb P sensitive PU foam dressing, sterile, heel, 23,5x25cm, 10 pieces	235 x 250 (175x190)mm	HSF250235FH
Multisite Border	139367	Suprasorb P sensitive PU foam dressing, sterile, multisite, 12x15cm, 10 pieces	120 x 150 (70x100)mm	HSF150120FM
	139357	Suprasorb P sensitive PU foam dressing, sterile, multisite, 12x15cm, 10 pieces	120 x 150 (70x100)mm	HSF150120FM
	142075	Suprasorb P sen Multi b 7,5x9,5 10ste Silicone Foam Dressing -multisite border	75x95(35x55)mm	HSF095075FM
	142076	Suprasorb P sen Multi b 16x20 10ste Silicone Foam Dressing -multisite border	160x200(115x155)mm	HSF200160FM
	142078	Suprasorb P sen Multi b 7,5x9,5 10ST LPPR Silicone Foam Dressing -multisite border	75x95(35x55)mm	HSF095075FM
	142079	Suprasorb P sen Multi b 16x20 10ST LPPR Silicone Foam Dressing -multisite border	160x200(115x155)mm	HSF200160FM
Multisite Border Lite	142077	Suprasorb P sen Multi b Lite 7,5x9,5 10st Silicone Foam Dressing -multisite border lite	75x95(35x55)mm	HSF095075L3M
	142080	Suprasorb P sen Mul b Lite 7,5x9,5 10ST LPPR Silicone Foam Dressing -multisite border lite	75x95(35x55)mm	HSF095075L3M