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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 P SensiFlex®
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:	CE 0123
(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:

Place and Date of Issue:

Huizhou 2025-05-13

Yang Zhang

Person Responsible for Regulatory Compliance

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Annex I

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

L&R REF	L&R description	Size	Foryou REF code
400200	Suprasorb P SensiFlex border 15x15 10ste	150 x 150 (105x105)mm	HSF150150FB
400201	Suprasorb P SensiFlex b lite 15x15 10ste	150 x 150 (105 x 105)mm	HSF150150L3B
400202	Suprasorb P SensiFlex border 20x20 10ste	200 x 200 (150x150)mm	HSF200200FB
400203	Suprasorb P SensiFlex b lite 10x20 10ste	200x100 (150x50)mm	HSF200100L3B
400204	Suprasorb P SensiFlex border 15x20 10ste	200x150 (150 x 105)mm	HSF200150FB
400205	Suprasorb P SensiFlex b lite 15x20 10ste	200x150 (150 x 105)mm	HSF200150L3B
400206	Suprasorb P SensiFlex border 10x30 5ste	300x100(240x50)mm	HSF300100FB
400207	Suprasorb P SensiFlex mu b 7,5x9,5 10ste	95×75(55×35)mm	HSF095075FBK
400208	Suprasorb P SensiFlex mu b 16x20 10ste	200×160(155×115)mm	HSF200160FBK
400209	Suprasorb P SensiFlex mu bL 7,5x9,5 10st	95×75(55×35)mm	HSF095075L3BK
400210	Suprasorb P SensiFlex mu b 12x15 10ste	150 x 120 (100 x 70)mm	HSF150120FBK
400211	Suprasorb P SensiFlex b 20x20 10ST LPPR	200 x 200 (150x150)mm	HSF200200FB
400212	Suprasorb P SensiFlex bL 10x20 10ST LPPR	200x100 (150x50)mm	HSF200100L3B
400213	Suprasorb P SensiFlex b 10x30 10ST LPPR	300x100(240x50)mm	HSF300100FB
400214	Suprasorb P SensiFlex b 15x15 10ST LPPR	150 x 150 (105x105)mm	HSF150150FB
400215	Suprasorb P SensiFlex mu b 7,5x9,5/10 LPPR	95×75(55×35)mm	HSF095075FBK
400216	Suprasorb P SensiFlex mu b 16x20/10 LPPR	200×160(155×115)mm	HSF200160FBK
400217	Suprasorb P SensiFlex mubL 7,5x9,5/10 LPPR	95×75(55×35)mm	HSF095075L3BK
400218	Suprasorb P SensiFlex mu b 12x15/10 LPPR	150 x 120 (100 x 70)mm	HSF150120FBK
400260	Suprasorb P SensiFlex multiBorder MUSTER	95×75(55×35)mm	HSF095075FBK
400261	Suprasorb P SensiFlex mu BordLite MUSTER	95×75(55×35)mm	HSF095075L3BK
401100	Suprasorb P SensiFlex border 10x10 10ste	100×100(62×62)mm	SF100100BHBBP

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401101	Suprasorb P SensiFlex border 7,5x8,5 10ste	75×85(45×50)mm	SF8575BHBBP
401102	Suprasorb P SensiFlex b lite 5x5 10ste	50×50(25×25)mm	SF5050BJDBP
401103	Suprasorb P SensiFlex b lite 5x10 10ste	50×100(25×60)mm	SF10050BJDBP
401104	Suprasorb P SensiFlex b lite 10x10 10ste	100×100(62×62)mm	SF100100BJDBP
401105	Suprasorb P SensiFlex b lite 7,5x8,5 10ste	75×85(45×50)mm	SF8575BJDBP
401106	Suprasorb P SensiFlex border 5x5 10ste	50×50(25×25)mm	SF5050BHBBP
401107	Suprasorb P SensiFlex border 7,5x7,5 10ste	75×75(45×45)mm	SF7575BHBBP
401108	Suprasorb P SensiFlex b lite 7,5x7,5 10ste	75×75(45×45)mm	SF7575BJDBP
401109	Suprasorb P SensiFlex b 12,5x12,5 10ste	125×125(85×85)mm	SF125125BHBBP
401110	Suprasorb P SensiFlex b lite 9x15 10ste	90×150(50×105)mm	SF15090BJDBP
401111	Suprasorb P SensiFlex b lite 6x12 10ste	120×60(80×30)mm	SF12060BJDBP
401112	sacrum, 17x17,5cm	170×175(120×125)mm	SF175170BHBBR
401113	sacrum, 23x23cm	230×230(165×170)mm	SF230230BHBBR
401114	heel, 23,5x25cm	235×250(175×190)mm	SF250235BHBBH
401115	Suprasorb P SensiFlex b 10x10 10ste LPPR	100×100(62×62)mm	SF100100BHBBP
401116	Suprasorb P SensiFlex b 7,5x8,5 10ste LPPR	75×85(45×50)mm	SF8575BHBBP
401117	Suprasorb P SensiFlex bL 5x5 10ste LPPR	50×50(25×25)mm	SF5050BJDBP
401118	Suprasorb P SensiFlex bL 5x10 10ste LPPR	50×100(25×60)mm	SF10050BJDBP
401119	Suprasorb P SensiFlex bL 10x10 10ste LPPR	100×100(62×62)mm	SF100100BJDBP
401120	Suprasorb P SensiFlex bL 7,5x8,5 10ste LPPR	75×85(45×50)mm	SF8575BJDBP
401121	Suprasorb P SensiFlex bL 6x12 10ste LPPR	120×60(80×30)mm	SF12060BJDBP
401122	Suprasorb P SensiFlex b 12,5x12,5 10ste LP	125×125(85×85)mm	SF125125BHBBP
401123	Suprasorb P SensiFlex bL 9x15 10ste LPPR	90×150(50×105)mm	SF15090BJDBP
401124	sacrum, 17x17,5cm, LPPR	170×175(120×125)mm	SF175170BHBBR

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401125	sacrum, 23x23cm, LPPR	230×230(165×170)mm	SF230230BHBBR
401126	heel, 23,5x25cm, LPPR	235×250(175×190)mm	SF250235BHBBH