

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: Super Absorbent Dressing
Trade Name: ConvaMax™
Type/Specification: See Annex I
Basic UDI-DI: Non-Adherent: 69406101SP0001C4; Adherent: 69406101SP0002C6; Border: 69406101SP0003C8
EMDN Code: M040414 MULTILAYER ABSORBENT DRESSINGS
GMDN Code: 46854
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 10993-5:2009, 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, 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 13726-3:2003, 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:



Yang Zhang

Person Responsible for Regulatory Compliance

Place and Date of Issue:

Huizhou 2024-09-29

Annex I

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

No.	PRODUCT NAME	SAP Item No.	ICC
1	CONVAMAX SUPABS N/ADH 7.5X7.5CM 1X10 INT	1727554	422566
2	CONVAMAX SUPABS N/ADH 10X10CM 1X10 INT	1727555	422567
3	CONVAMAX SUPABS N/ADH 10X20CM 1X10 INT	1727556	422568
4	CONVAMAX SUPABS NADH 12.5X12.5CM 1X10INT	1727557	422569
5	CONVAMAX SUPABS N/ADH 15X15CM 1X10 INT	1727558	422570
6	CONVAMAX SUPABS N/ADH 15X20CM 1X10 INT	1727559	422571
7	CONVAMAX SUPABS N/ADH 20X20CM 1X10 INT	1727560	422572
8	CONVAMAX SUPABS N/ADH 20X30CM 1X10 INT	1727561	422573
9	CONVAMAX SUPABS N/ADH 20X40CM 1X10 INT	1727562	422574
10	CONVAMAX SUPABS ADH 7.5X7.5CM 1X10 INT	1727563	422575
11	CONVAMAX SUPABS ADH 10X10CM 1X10 INT	1727564	422576
12	CONVAMAX SUPABS ADH 10X20CM 1X10 INT	1727565	422577
13	CONVAMAX SUPABS ADH 12.5X12.5CM 1X10 INT	1727566	422578
14	CONVAMAX SUPABS ADH 15X15CM 1X10 INT	1727567	422579
15	CONVAMAX SUPABS ADH 15X20CM 1X10 INT	1727568	422580
16	CONVAMAX SUPABS ADH 20X20CM 1X10 INT	1727569	422581
17	CONVAMAX SUPABS ADH 20X30CM 1X10 INT	1727570	422582
18	CONVAMAX SUPABS ADH 20X40CM 1X10 INT	1727571	422583
19	CONVAMAX SUPABS N/ADH 15X15CM 1X3 ES	1735278	423523
20	CONVAMAX SUPABS ADH 10X10 1X3 STER ES	1749906	424004

21	CONVAMAX SUPABS N/ADH 7.5X7.5CM 1X10 IN2	1737178	422566
22	CONVAMAX SUPABS N/ADH 10X10CM 1X10 IN2	1737179	422567
23	CONVAMAX SUPABS N/ADH 10X20CM 1X10 IN2	1737180	422568
24	CONVAMAX SUPABS NADH 12.5X12.5CM 1X10IN2	1737181	422569
25	CONVAMAX SUPABS N/ADH 15X15CM 1X10 IN2	1737182	422570
26	CONVAMAX SUPABS N/ADH 15X20CM 1X10 IN2	1737183	422571
27	CONVAMAX SUPABS N/ADH 20X20CM 1X10 IN2	1737184	422572
28	CONVAMAX SUPABS N/ADH 20X30CM 1X10 IN2	1737185	422573
29	CONVAMAX SUPABS N/ADH 20X40CM 1X10 IN2	1737186	422574
30	CONVAMAX SUPABS ADH 7.5X7.5CM 1X10 IN2	1737187	422575
31	CONVAMAX SUPABS ADH 10X10CM 1X10 IN2	1737188	422576
32	CONVAMAX SUPABS ADH 10X20CM 1X10 IN2	1737189	422577
33	CONVAMAX SUPABS ADH 12.5X12.5CM 1X10 IN2	1737190	422578
34	CONVAMAX SUPABS ADH 15X15CM 1X10 IN2	1737191	422579
35	CONVAMAX SUPABS ADH 15X20CM 1X10 IN2	1737192	422580
36	CONVAMAX SUPABS ADH 20X20CM 1X10 IN2	1737193	422581
37	CONVAMAX SUPABS ADH 20X30CM 1X10 IN2	1737194	422582
38	CONVAMAX SUPABS ADH 20X40CM 1X10 IN2	1737195	422583