

Declaration of Conformity

1. Manufacturer: Xuchang Zhende Surgical Dressing Co., Ltd.

Site 1: No. 1 Jinhui Road, Industry Cluster District, Yanling County, 461200,
Xuchang City, Henan Province, China

Site 2(Legal Manufacturer): Area A, Baihua Road East, South Side of Erji river,
Industry Cluster District, Yanling County 461200 Xuchang, Henan PEOPLE'
S REPUBLIC OF CHINA

2. EC Representative: Shanghai International Holding Corp. GmbH (Europe)

Eiffestraße 80, 20537 Hamburg, Germany

3. Product name Procedural Dressing Trays

Product type: Dressing Tray for Wound care /Dressing change tray

UMDNS Code: 17168

4. Classification (MDD, Annex IX): IIa, Rule 7

Conformity Assessment Route: Annex II section 3

5. Statement:

We herein declare in our own responsibility that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.

6. DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).

7. Standard Applied: EN ISO 15223-1:2021 EN 14079:2003
EN ISO 13485:2016 EN ISO 14971:2012

8. Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr, 65, 80339
München, Germany

NB Identification number: 0123

9. (EC) Certificate(s): G1 109397 0004 Rev.00

Expire date of the Certificate: 2024-03-03

Start of CE Marking: 2018-09-30

Signature:



Name: Chen Ming

Date: 2022.05.27

Position: Regulatory Director

Product List

No	REF	ZD Code	NAME SET ENGLISH
1	145727	N11000111K-128	Raucoset® Gauze Balls Set
2	145832	N11000111K-129	Raucoset® Suture Set
3	145329	N11000111K-130	Raucoset® Catheter Connector Set
4	145749	N11000111K-131	Raucoset® Probe Set
5	145551	N11000111K-132	Raucoset® Vulval Treatment Set
6	145306	N11000111K-134	Raucoset® Buttoned Probe
7	145965	N11000111K-135	Raucoset® Probe Set without ampoules
8	145499	N11000111K-136	Raucoset® Connector Set C
9	145455	N11000111K-138	Raucoset® Disinfection Set
10	145600	N11000111K-140	Raucoset® OR Infusion Set
11	145618	N11000111K-141	Raucoset® Dressing Set No. 8
12	145834	N11000111K-143	Raucoset® Probe Set No. 2
13	145892	N11000111K-147	Raucoset® Probe Set No. 1 (S)
14	145912	N11000111K-149	Raucoset® Tongue Spatula Set
15	145346	N11000111K-155	Raucoset® Emesis Basin
16	145356	N11000111K-159	Raucoset® Disinfection Set
17	145365	N11000111K-160	Raucoset® Dressing Set No. 1
18	145371	N11000111K-161	Raucoset® Dialysis Set
19	145390	N11000111K-162	Raucoset® Narcosis Set
20	145468	N11000111K-164	Raucoset® Dialysis Set
21	145718	N11000111K-168	Raucoset® Catheter Set
22	145305	N11000111K-175	Raucoset® Home Care Set
23	145055	N11000111K-176	Raucoset® Mouth Care Set
24	145722	N11000111K-127	Raucoset® Set 3 Gauze Balls NW 64
25	145573	N11000111K-169	Raucoset® Dressing Set No. 7
26	145553	N11000111K-133	Raucoset® Probe Set
27	145314	N11000111K-172	Raucoset® Nonwoven Injection Set
28	145451	N11000111K-137	Raucoset® Probe Set
29	145458	N11000111K-139	Raucoset® Probe Set
30	145802	N11000111K-142	Raucoset® Dressing Set No. 4
31	145833	N11000111K-170	Raucoset® Dressing Set No. 1
32	145836	N11000111K-174	Raucoset® Dressing Set No. 2
33	145838	N11000111K-144	Raucoset® Disinfection Set S.O.P.
34	145841	N11000111K-165	Raucoset® Dressing Set No. 3
35	145844	N11000111K-145	Raucoset® Disinfection Set, alternative
36	145850	N11000111K-173	Raucoset® Dressing Set No. 6
37	145876	N11000111K-146	Raucoset® Universal Dressing Set
38	145893	N11000111K-148	Raucoset® Set anatomical forceps, blue
39	145035	N11000111K-180	Raucoset® 5 Gynaecology Dressings
40	145087	N11000111K-171	Raucoset® Set 5 Gauze Balls 62
41	145092	N11000111K-150	Raucoset® Venous Puncture Set
42	145106	N11000111K-151	Raucoset® Disinfection Set
43	145304	N11000111K-152	Raucoset® Anaesthesia Set
44	145313	N11000111K-153	Raucoset® Disinfection Set
45	145318	N11000111K-154	Raucoset® Dressing Set No. 5
46	145319	N11000111K-167	Raucoset® Dressing Set
47	145442	N11000111K-163	Raucoset® Probe Set
48	145034	N11000111K-181	Raucoset® 10 Gynaecology Dressings