



Declaration of Conformity

1. Manufacturer:

Name: Xuchang Zhende Surgical Dressing Co., Ltd

Address:

Site 1: No. 1 Jinhui Road, Industry Cluster District, Yanling County, 461200,
Xuchang City, Henan Province, PEOPLE'S REPUBLIC OF 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

SRN: CN-MF-000009222

2. European Authorized Representative:

Name: Shanghai International Holding Corp.GmbH (Europe)

Address: Eiffestraße 80, 20537 Hamburg, GERMANY

SRN: DE-AR-000000001

3. Notified Body:

Name: TÜV SÜD Product Service GmbH, Ridlerstr, 65, 80339 München, Germany

Identification number: 0123

4. Product Name: Wound Dressing Kits

(For product details please refer to attached the Product List)

Basic UDI-DI: 697240330WDK000001R7,697240330WDK000002R9

697240330WDK000003RB,697240330WDK000004RD,697240330WDK000005RF

697240330WDK000006RH,697240330WDK000007RK,697240330WDK000008RM

697240330WDK000009RP,697240330WDK000010R8

5. GMDN Code: 62744

6. Intended Use: Wound Dressing Kits are disposable trays used to perform various treatments on patients during medical Procedures. The trays are used in hospitals and clinics, mainly by professional physicians or nurses.

7. Classification: IIa

Based on MDR EU2017/745 Annex VIII Rule7

The specific sentence is: All surgically invasive devices intended for



short-term use are classified as IIa

8. Conformity Assessment Route: MDR Annex XI Part A

9. Statement:

We hereby declare the compliance of the above medical device with the applicable requirements of Medical Device Regulation: REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices.

The EU declaration of conformity is issued under the sole responsibility of Xuchang Zhende Surgical Dressing Co., Ltd

10. Standard Applied:

EN ISO15223-1:2021 EN ISO 13485:2016 EN ISO 14971:2019

10. CS: NA

12. (EU) Certificate(s) No.: G20 109397 0008 Rev.00

Expire date of the certificate: 2030-04-22

Issue date of the certificate: 2025-04-23

Signature: 

Name: Chen Ming

Place, Date of Issue: Xuchang, 2025-04-24

Position: Regulatory Director



Product List

S/N	REF	Product description	Basic UDI-DI
1	166841	Raucoset®Dressing Set No. 3.	697240330WDK000010R8
2	166836	Raucoset®DressingSetNo.2	697240330WDK000010R8
3	166573	Raucoset®DressingSetNo.7	697240330WDK000010R8
4	166087	Raucoset® Set5GauzeBalls62	697240330WDK000010R8
5	166850	Raucoset® DressingSetNo.6	697240330WDK000010R8
6	166314	Raucoset® NonwovenInjectionSet	697240330WDK000010R8
7	157445	Zhende KathSet Uhs L 145888	697240330WDK000003RB
8	166319	Raucoset® DressingSet	697240330WDK000010R8
9	166833	Raucoset® DressingSetNo.1	697240330WDK000010R8
10	145718	Raucoset® CatheterSet	697240330WDK000010R8
11	157446	Zhende KathSet Basic 145889	697240330WDK000003RB
12	166305	Raucoset® HomeCareSet	697240330WDK000010R8
13	166365	Raucoset® DressingSetNo.1	697240330WDK000010R8
14	145356	Raucoset® DisinfectionSet	697240330WDK000010R8
15	166318	Raucoset® DressingSetNo.5	697240330WDK000010R8
16	145832	Raucoset® SutureSet	697240330WDK000006RH
17	166551	Raucoset® VulvalTreatmentSet	697240330WDK000010R8
18	145442	Raucoset® ProbeSet	697240330WDK000010R8
19	145451	Raucoset® ProbeSet	697240330WDK000010R8
20	166455	Raucoset® DisinfectionSet	697240330WDK000010R8
21	145893	Raucoset®Setanatomicalforceps,blue	697240330WDK000010R8
22	145499	Raucoset® ConnectorSetC	697240330WDK000010R8
23	145892	Raucoset® ProbeSetNo.1(S)	697240330WDK000010R8
24	166600	Raucoset® ORInfusionSet	697240330WDK000010R8
25	145390	Raucoset® NarcosisSet	697240330WDK000010R8



26	145553	Raucoset® ProbeSet	697240330WDK000010R8
27	145034	Raucoset® 10GynaecologyDressings	697240330WDK000010R8
28	145035	Raucoset® 5GynaecologyDressings	697240330WDK000010R8
29	145834	Raucoset® ProbeSetNo.2	697240330WDK000010R8
30	145304	Raucoset® AnaesthesiaSet	697240330WDK000010R8
31	166092	Raucoset® VenousPunctureSet	697240330WDK000010R8
32	145727	Raucoset® GauzeBallsSet	697240330WDK000010R8
33	166802	Raucoset® DressingSetNo.4	697240330WDK000010R8
34	166844	Raucoset® DisinfectionSet,alternative	697240330WDK000010R8
35	145749	Raucoset® ProbeSet	697240330WDK000010R8
36	145313	Raucoset® DisinfectionSet	697240330WDK000010R8
37	145329	Raucoset® CatheterConnectorSet	697240330WDK000010R8
38	166838	Raucoset® DisinfectionSetS.O.P.	697240330WDK000010R8
39	166106	Raucoset® DisinfectionSet	697240330WDK000010R8
40	145458	Raucoset® ProbeSet	697240330WDK000010R8
41	166618	Raucoset® DressingSetNo.8	697240330WDK000010R8
42	145876	Raucoset® UniversalDressingSet	697240330WDK000010R8
43	166371	Raucoset® DialysisSet	697240330WDK000002R9
44	145722	Raucoset® Set3GauzeBallsNW64	697240330WDK000010R8
45	145306	Raucoset® ButtonedProbe	697240330WDK000010R8
46	145314	Raucoset® NonwovenInjectionSet	697240330WDK000010R8
47	145371	Raucoset® DialysisSet	697240330WDK000002R9
48	145551	Raucoset® VulvalTreatmentSet	697240330WDK000010R8
49	145802	Raucoset® DressingSetNo.4	697240330WDK000010R8
50	145838	Raucoset® DisinfectionSetS.O.P.	697240330WDK000010R8
51	166468	Raucoset® DialysisSet	697240330WDK000002R9