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

Name: Chen Ming Position: Regulatory Director

Product List

S/N	REF	Product name
1	990200	wound set 1
2	990201	wound set
3	990202	wound set
4	990501	Urinary catheter set Basis 1
5	990203	wound set
6	990503	Urinary catheter set Basis 4
7	990205	wound set
8	990207	wound set
9	990208	wound set 2
10	990502	Urinary catheter set Basis 2
11	990209	wound set
12	990281	dialysis set
13	990360	desinfection set
14	990361	desinfection set
15	990210	wound set