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 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: TÜVSÜD Product Service GmbH, Ridlerstr, 65, 80339 München, Germany
Identification number: 0123

4. Product Name： Dressing pack (For product details please refer to attached the Product List)
Basic UDI-DI: 697240330DP00000132

5. GMDN code: 33961

6. Intended use： Dressing Pack is used for wound treatment and examination.

7. Classification: I sterile
Based on MDR EU2017/745 Annex VIII rule 4,
The specific sentence is:
All non-invasive devices which come into contact with injured skin or mucous membrane are classified as: class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates;

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 ISO 13485:2016 EN ISO 14971:2019 EN ISO 15223-1:2021

11. CS: NA

12. (EU) Certificate(s) No.: G21 109397 0009 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	990204	wound set 1
2	990206	wound set