Declaration of Conformity

1. **Manufacturer:** Name: Zhende Medical Co.,Ltd.
   Address: Gaobu Town, 312035, Shaoxing, Zhejiang, China.
   SRN: CN-MF-000009961
2. **European representative:**
   Name: Shanghai International Holding Corp.GmbH (Europe)
   Address: Eiffestraße 80, 20537 Hamburg, Germany.
   SRN: DE-AR-000000001
3. **Notified Body:** TüV SüD Product Service GmbH
   Address: Ridlerstr, 65, 80339 München, Germany
   Identification number: 0123
4. **Product Name:** Sterile Adhesive Surgical Dressing
   (including Non-woven dressing type and transparent dressing type)
5. **Basic UDI-DI:** 69593857SASD0000013M (EO sterile)
   69593857SASD0000023P (gamma sterile)
   69593857SASD0000033R (E-beam sterile)
6. **EMDN Code:** M04010101; M04010102
7. **Intended Use:**

Adhesive surgical dressing is intended to be used as a primary or secondary dressing over acute wounds, surgical sites and chronic wounds fixation and protecting the wound from infection.

8. **Classification:** Is

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 Is if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates.

9. **Conformity Assessment Route:** MDR Annex XI Part A
10. **Statement:**
    We 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 Zhende Medical Co., Ltd.
11. **CS**: N/A

12. Standard Applied:

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

13. (EC) Certificate(s):

Number of the Certificate: G26 095972 0019 Rev. 00

Expire date of the Certificate: 2031-01-28

Issue date of the certificate: 2025-12-16

Place, Date of Issue the declaration: Shaoxing, 2026.02.05

Signature:

Name: Yu Jiangfeng Position: Senior Regulatory Manager