



Declaration of Conformity

1. Manufacturer:

Name: Zhende Medical Co., Ltd.

Address: Gaobu Town, 312035, Shaoxing, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

SRN: CN-MF-000009961

2. European representative:

Name: Shanghai International Holding Corp.GmbH (Europe)

Address: Eiffestraße 80, 20537 Hamburg, GERMANY

3. NB: TÜV SÜD Product Service GmbH, Ridlerstr, 65, 80339 München, Germany

Identification number: 0123

4. Product name: Skin Closure Strips**Basic UDI-DI:** 69593857SCS000001GK**5. GMDN Code:** 32207**6. Intended use:** Skin Closure Strips are used to secure, close and support small cuts and wounds. They are applied across the laceration in a manner which pulls the skin on either side of the wound together.**7. Classification:** Class 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: Annex XI Part A**9. 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.

10. Common Specification: NA**11. Standard Applied:**

EN ISO 15223-1:2021

EN ISO 13485:2016

EN ISO 14971:2019

12. (EC) Certificate(s):

Number of the Certificate: G21 095972 0015 Rev. 01

Expire date of the Certificate: 2026-1-28

Place, Issue date of the certificate: 2024-6-26

Date of Issue: 2024.6.28

Signature: A handwritten signature in black ink, appearing to be 'N. J. Wang'.

ZDYL/QSMDR-24
Zhende Medical Co., Ltd.



Name: Chen Ming

Position: Regulatory Director