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. **Product name:** Medical Adhesive Tape
   Basic UDI-DI: 69593857MT000001WX
4. **EMDN Code:** M04010201 (Non-woven tape); M04010299(PE tape, Silk tape, Zinc Oxide tape, Cotton tape); M04010203(Silicone tape)
5. **Intended use:** Medical Adhesive Tape is mainly used for infusion tube fixation, wound dressing fixation and medical supplies fixation.
6. **Classification:** Class I non-sterile
   Based on MDR EU2017/745 Annex VIII rule 1.
   The specific sentence is: All non-invasive devices are classified as class I, unless one of the rules set out hereinafter applies.
7. **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.

8. **Common Specification:** NA
9. **Standard Applied:**

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

Date of Issue: 2024.11.26

Signature:

Name: Chen Ming

Position: Regulatory Director

Product List

No.	Product Name	REF	Description
1	Silkafix adhesive tape	401620	100% polyester+ hot melt adhesive
2	Silkafix adhesive tape	401621	100% polyester+ hot melt adhesive
3	Silkafix adhesive tape	401622	100% polyester+ hot melt adhesive
4	Silkafix adhesive tape	401623	100% polyester+ hot melt adhesive
5	Silkafix adhesive tape	401624	100% polyester+ hot melt adhesive
6	Silkafix adhesive tape	401625	100% polyester+ hot melt adhesive
7	Silkafix adhesive tape	401626	100% polyester+ hot melt adhesive
8	Ratioline adhesive tape	401640	100% polyester+ hot melt adhesive