



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 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: 2024.3.8

Signature: 

Name: Chen Ming

Position: Regulatory Director