

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 Tape

Basic UDI-DI: 69593857MT000001WX

Detailed information refer to Product List

4. GMDN Code: 34831 Adhesive tape(including Non-woven tape, Silk tape, Zinc Oxide tape, Cotton tape, etc)

58300 PE tape

58749 Silicone tape

5. Intended use: Medical Tape products are mainly used infusion tube fixation, wound dressing fixation and medical supplies fixation. They are used in hospitals, clinics, and in homecare, mainly by professional physicians, nurses or family members.

6. Classification: Class I non-sterile

Based on MDR EU2017/745 Annex VIII rule 1

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.

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 14971:2012

Place,Date of Issue: Shaoxing,Zhejiang,2021.08.03

Signature: 

Name: Chen Ming

Position: Regulatory Director



Product List

No.	REF	Description	Size	Package
1	14385 3	Silkafix Rollenpfl. 5m	1.25cm*5 m	plastic core,12pcs/boxes, 48boxes/carton
2	14385 4	Silkafix Rollenpfl. 5m	2.5cm*5m	plastic core,16pcs/boxes, 12boxes/carton
3	14385 5	Silkafix Rollenpfl. 5m	5cm*5m	plastic core,18pcs/boxes, 36boxes/carton
4	14385 6	Silkafix Rollenpfl. 5m	2.5cm*5m	cardboard core, 8pcs/boxes, 30boxes/carton
5	14385 7	Silkafix Rollenpfl. 9,2m	1.25cm*9 m	cardboard core,12pcs/boxes, 24boxes/carton
6	14385 8	Silkafix Rollenpfl. 9,2m	2.5cm*9m	cardboard core,6pcs/boxes, 36boxes/carton
7	14385 9	Silkafix Rollenpfl. 9,2m	5cm*9m	cardboard core,12pcs/boxes, 32boxes/carton
8	14386 8	OTC Rollenpfl. Acetat 5m	2.5cm*5m	plastic core/blister box,4pcs/boxes, 32boxes/carton