

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 dressing roll

Basic UDI-DI: 69593857MDR000001CB

Detailed information refer to Product List in Page 2

4. GMDN Code: 34831(Non-woven dressing roll), 58300(Transparent dressing roll)

5. Intended use: Medical dressing roll is used to protect different types of tubes and primary dressings, can act as an excellent secondary dressing for gauze, foams, gels, etc.

6. Classification: Class I non-sterile

Based on MDR EU2017/745 Annex VIII Rule1

The specific sentence is:

All non-invasive devices are classified as 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

EN ISO 13485:2016

EN ISO 14971:2019

EN ISO 15223-1:2021

Place, Date of Issue: Shaoxing, Zhejiang. 2022.02.25

Signature:



Name: Chen Ming

Position: Regulatory Director



Product List

Product name	Specification	REF no.	UDI-DI
Non-woven dressing roll, 10m x 5cm	5cm*10m, 1 roll/box, 24 boxes/carton	135315	6926515454647
Non-woven dressing roll, 10m x 10cm	10cm*10m, 1 roll/box, 24 boxes/carton	135316	6926515454661
Non-woven dressing roll, 10m x 15cm	15cm*10m, 1 roll/box, 24 boxes/carton	135317	6926515454685
Non-woven dressing roll, 10m x 20cm	20cm*10m, 1 roll/box, 24 boxes/carton	135318	6926515454708