



Declaration of Conformity

1. Manufacturer:

Name: Zhende Medical Co.,Ltd

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

SRN: The application of SRN is in process now

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**4. GMDN Code:** 16866(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

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 15223-1:2016

EN ISO 1041:2008+A1:2013

Date of issue: 2021.2.10

Signature:

Name: Chen Ming

Position: Regulatory Director

ZDYL/QSMDR-37
Zhende Medical Co., Ltd



Product List

S/N	Specification	REF
1	Non-woven dressing roll 15*2000cm	138940
2	Non-woven dressing roll 5*1000cm	138941
3	Non-woven dressing roll 10*1000cm	138942
4	Non-woven dressing roll 15*1000cm	138943
5	Non-woven dressing roll 20*1000cm	138944
6	Non-woven dressing roll 30*1000cm	138945
7	Non-woven dressing roll 10*2000cm	138946
8	Non-woven dressing roll 5*1000cm	190200
9	Non-woven dressing roll 10*1000cm	190201
10	Non-woven dressing roll 15*1000cm	190202
11	Non-woven dressing roll 20*1000cm	190203