



Declaration of Conformity

1. Manufacturer:

Name: Henan Zhende Medical Products Co., Ltd.

Address: Baihua Road West, North Side of jinhui Road, Industry Cluster District, Yanling County,
461200 Xuchang City, Henan Province, PEOPLE'S REPUBLIC OF CHINA

SRN: CN-MF-000009621

2. European Representative:

Name: Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffestraße 80, 20537 Hamburg, Germany.

3. Product Name: Non-sterile non-woven products

Basic UDI-DI: 697240342NNWP000001W9

4. GMDN Code: 48131

5. Intended use:

Non-sterile non-woven products are intended for absorbing the blood or exudates in operation. It can be used to cleaning the wound to prevent the wounds infection or cross infection. It contact breached or otherwise compromised body surface.

6. Classification: Class I

Based on MDR EU2017/745 Annex VIII rule 4

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 hereby 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 Henan Zhende Medical Products Co., Ltd.

8. CS: NA



9. Standard Applied:

ISO15223-1:2021

EN ISO 13485:2016

EN ISO 14971:2012

Place, Date of Issue the declaration: Shaoxing, 2021-12-31

Signature: 

Name: Chen Ming

Position: Regulatory Director

Product list

S/N	REF	Product
1	221604	Nonwoven Swabs 30g/m ² 10*10cm-4P
2	221602	Nonwoven Swabs 30g/m ² 5*5cm-4P
3	221603	Nonwoven Swabs 30g/m ² 7.5*7.5cm-4P
4	7010	Nonwoven Swabs 30g/m ² 5*5cm-4P
5	7020	Nonwoven Swabs 30g/m ² 10*10cm-4P
6	7025	Nonwoven Swabs 30g/m ² 10*20cm-4P
7	7015	Nonwoven Swabs 30g/m ² 7.5*7.5cm-4P