Declaration of Conformity

1. Manufacturer:

Name: Xuchang Zhende Surgical Dressing Co., Ltd

Address: Site 1: No. 1 Jinhui Road, Industry Cluster District, Yanling County, 461200, Xuchang City, Henan Province, PEOPLE'S REPUBLIC OF CHINA

Site 2 (Legal Manufacturer): Area A, Baihua Road East, South Side of Erji river, Industry Cluster District, Yanling County 461200 Xuchang, Henan, 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: Non-sterile gauze products

Basic UDI-DI: 697240330NSGP000001M9

4. GMDN Code: 58802, 48133, 48126

5. Intended use:

Non-sterile gauze products are intended for absorbing the blood or exudates on surface wound for medical purposes. It can be used to clean the wound to prevent the wounds infection or cross infection.

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. Conformity Assessment Route: MDR EU2017/745 Annex II and Annex III

8. 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 Xuchang Zhende Surgical Dressings Co., Ltd.

9. Common Specifications: NA

10. Applicable Standards:

EN ISO 13485:2016 EN ISO 14971:2019 EN ISO 15223-1:2016

EN 1041:2008+A1:2013 EN 14079:2003

Place, Date of Issue: Xuchang, Henan, 2021-06-15

Signature: 

Name: Chen Ming

Position: Regulatory Director

XCZD/QSMDR-09
Xuchang Zhende Surgical Dressing Co., Ltd

Product List

S/N	Product name	RFE	Specification	Product code
1	Eiger Gazekompressen (Cutting Gauze)	137170	40s/30*28 6*8cm	E0106088007
2	Eiger Gazekompressen (Cutting Gauze)	137171	40s/30*28 8*12cm	E0108128007
3	Eiger Gazekompressen (Cutting Gauze)	137172	40s/30*28 10*10cm	E0110108007
4	Eiger Gazekompressen (Cutting Gauze)	137173	40s/30*28 4*6cm	E0104068007
5	Eiger Gazekompressen (Cutting Gauze)	137874	40s/30*28 23*20cm	E0120232007