Declaration of Conformity

1.Manufacturer: Xuchang Zhende Surgical Dressing Co.,Ltd.

Site 1: No. 1 Jinhui Road, Industry Cluster District, Yanling County, 461200， Xuchang City, Henan Province, 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

2.EC Representative: Shanghai International Holding Corp. GmbH (Europe)

Eiffestraβe 80, 20537 Hamburg, Germany

3.Product name Procedural Dressing Trays

Product type: Dressing Tray for Wound care /Dressing change tray

UMDNS Code: 17168

4.Classification (MDD, Annex IX): IIa, Rule 7

Conformity Assessment Route: Annex II section 3

5.Statement:

We herein declare in our own responsibility that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.

6.DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).

7.Standard Applied: EN ISO 15223-1:2021 EN 14079:2003

EN ISO 13485:2016 EN ISO 14971:2019

8.Notified Body:TÜV SÜD Product Service GmbH, Ridlerstr, 65, 80339 München, Germany

NB Identification number: 0123

9.(EC) Certificate(s): G1 109397 0004 Rev.00

Expire date of the Certificate: 2024-03-03

Start of CE Marking: 2018-09-30

Signature:  Date: 2022.05.27

Name: Chen Ming Position: Regulatory Director

Product

REF	Description
DRESS001	1x plastic forceps with teeth, blue 14cm 1x plastic forceps blue, 12.5cm 1x plastic forceps green, 12.5cm 10x 30gsm nonwoven 7.5x7.5cm-4p 1x tissue drape 38x45cm, folded size 9.5x11.5cm
DRESS002	5x nonwoven swabs 7.5x7.5cm-4p,30gsm 5x balls nonwoven, 30gsm, dia.3cm 1x plastic forceps with teeth, blue 14cm 2x plastic forceps blue, 12.5cm 1x tissue drape 38x45cm, folded size 9.5x11.5cm
DRESS003	1x plastic forceps with teeth, blue 14cm 1x plastic forceps blue, 12.5cm 5x nonwoven swabs 7.5x7.5cm-4p 5x balls nonwoven, 30gsm, dia.3cm 1x tissue drape 38x45cm, folded size 9.5x11.5cm
DRESS005A	1x plastic tongue depressor 1x plastic forceps with teeth, blue 14cm 5x 30gsm nonwoven 7.5x7.5cm-4p, 50% viscose+50% polyester
DRESS018	Rigid blister, 3 compartments 5x 30gsm nonwoven 7.5x7.5cm-4p 5x balls woven, dia.3cm 1x plastic forceps with teeth, blue 1x plastic forceps blue 1x tissue drape 38x45cm