



Declaration of Conformity

- 1.Manufacturer: Xuchang Zhengde Environstar Medical Products Co.,Ltd.
Address:
Site 1: No.3, Weilai Road, Industry Cluster District, Yanling County 461200
Xuchang City, Henan Province, PEOPLE’S REPUBLIC OF CHINA
Site 2(Legal manufacturer): Area B, Baihua Road East, South Side of Erji
river, Industry Cluster District Yanling County 461200 Xuchang, Henan
PEOPLE’S REPUBLIC OF CHINA
- 2.European Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80 20537 Hamburg, Germany
- 3.Product Name Sterile Drapes
For product details please refer attached the Product List
- 4.UMDNS Code: 15775
5. Classification (MDD, Annex IX): I sterile, rule 1
- 6.Conformity Assessment Route: Annex V section 3

We herewith declare 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.

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: 2016

EN ISO 14971:2012

EN 1041:2008+A1:2013 EN ISO 13485:2016

EN 13795-1:2019

8. Notified Body:

TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München,
Germany

Identification number:

0123

(EC) Certificate(s):

No. G2S 109384 0004 Rev.00

Expire date of the Certificate:

2024-05-26

Start of CE Marking:

2010-11-26

Place, Date of Issue:

Xuchang, 2020-10-27



Signature: 

Date: 2021.03.25

Name: Chen Ming

Position: Regulatory Director

Product List

Customer REF No.	Product description	ZD REF	Sterility
63628	Adhesive Aperture Drape, variable	63628	Sterile
63629	Adhesive Aperture Drape, variable	63629	Sterile
63625	Adhesive Aperture, 60x75 cm, ap. 6x9.5cm	63625	Sterile
63690	Table Cover	63690	Sterile
63606	Adhesive OP-Sheet with reinforce	63606	Sterile
63605	Adhesive OP-Sheet with reinforce	63605	Sterile
63603	Adhesive OP-Sheet with reinforce	63603	Sterile
63604	Adhesive OP-Sheet with reinforce	63604	Sterile
63607	Adhesive OP-Sheet with reinforce	63607	Sterile
63611	Adhesive OP-Sheet w/o reinforce	63611	Sterile
63612	Adhesive OP-Sheet w/o reinforce	63612	Sterile
63613	Adhesive OP-Sheet w/o reinforce	63613	Sterile
63615	Adhesive OP-Sheet w/o reinforce	63615	Sterile
63616	Adhesive OP-Sheet w/o reinforce	63616	Sterile
63634	Extremity Drape 230x315cm, ap 7cm elasti	63634	Sterile
63633	Extremity Drape 230x315cm, ap 5cm elasti Sterile	63633	Sterile
63632	Hand/Foot Drape	63632	Sterile
63619	Sheet 90x75	63619	Sterile
63621	Aperture drape 90x75 with adhesive	63621	Sterile
63623	Aperture drape 50x60 with adhesive	63623	Sterile
63624	Aperture drape 120x150 with adhesive	63624	Sterile
63650	Split sheet	63650	Sterile
63651	Split sheet	63651	Sterile
63614	Adhesive Towel 100x100cm	63614	Sterile
63046	Mayo Stand Cover Primary Plus	63046	Sterile