



## Declaration of Conformity

1. Manufacturer: Xuchang Zhengde Environstar Medical Products Co., Ltd.

Site1: 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 Surgical Gowns (Product details refer to the attachment)

UMDNS Code: 11901

4. Classification (MDD, Annex IX):I sterile, rule 1

Conformity Assessment Route: Annex V section3

5. Statement:

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.

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: 2016      EN ISO 13485:2016

EN ISO 14971:2012      EN 13795-1:2019

8. Notified Body: TÜV SÜD Product Service GmbH,

Ridlerstr. 65, 80339,München, Germany




Identification number: 0123

9. (EC) Certificate(s): G2S 109384 0004 Rev.00

Expire date of the Certificate: 2024-05-26

Start of CE Marking: 2010-11-26

Signature: 

Place, date of issue: Xuchang, 2021.11.05

Name: Chen Ming

Position: Regulatory Director

## Product List

Customer REF	Description	ZD REF	Sterility
580100	Surgical Gown Primary Plus	580100	Sterile
580101	Surgical Gown Primary Plus	580101	Sterile
580102	Surgical Gown Primary Plus	580102	Sterile
580103	Surgical Gown Primary Plus	580103	Sterile
580104	Surgical Gown Primary Plus	580104	Sterile
580105	Surgical Gown Primary Plus	580105	Sterile
590100	Surgical Gown Primary Plus	590100	Sterile
590101	Surgical Gown Primary Plus	590101	Sterile
590102	Surgical Gown Primary Plus	590102	Sterile
590103	Surgical Gown Primary Plus	590103	Sterile
590104	Surgical Gown Primary Plus	590104	Sterile
590105	Surgical Gown Primary Plus	590105	Sterile
580200	Surgical Gown Primary Plus	580200	Sterile
580201	Surgical Gown Primary Plus	580201	Sterile
580202	Surgical Gown Primary Plus	580202	Sterile
580203	Surgical Gown Primary Plus	580203	Sterile
580204	Surgical Gown Primary Plus	580204	Sterile
580205	Surgical Gown Primary Plus	580205	Sterile
590200	Surgical Gown Primary Plus	590200	Sterile
590201	Surgical Gown Primary Plus	590201	Sterile
590202	Surgical Gown Primary Plus	590202	Sterile
590203	Surgical Gown Primary Plus	590203	Sterile
590204	Surgical Gown Primary Plus	590204	Sterile
590205	Surgical Gown Primary Plus	590205	Sterile
580106	Surgical Gown Primary Plus	580106	Sterile
580206	Surgical Gown Primary Plus	580206	Sterile