



## Declaration of Conformity

- 1.Manufacturer: Xuchang Zhengde Environstar Medical Products Co.,Ltd.  
Adress:  
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 (Hamburg)  
Eiffestrasse 80 20537 Hamburg Germany
- 3.Product Name Surgical Packs  
For product details please refer attached the Product List
- 4.UMDNS Codes: 13887
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 1041:2008+A1:2013  
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  
(EC) Certificate(s): No. G2S 109384 0004 Rev.00  
Expire date of the Certificate: 2024-05-26  
Start of CE Marking: 2016-11-07



Place, Date of Issue: Xuchang, 2020-10-27

Signature: 

Date: 2021.03.26

Name: Chen Ming

Position: Regulatory director

## Product List

Customer REF No.	Product description	ZD REF	Sterility
63710	Universal set Basic	63710	Sterile
63701	Universal Set w/o Mayo cover	63701	Sterile
63700	Universal Set w/Mayo cover	63700	Sterile
63702	Universal set Standard	63702	Sterile
63711	Basic Set	63711	Sterile
60711	Extremity Set	60711	Sterile
60811	Split Sheet Set	60811	Sterile
63731	Hand Set	63731	Sterile
63730	Hand/Foot Set	63730	Sterile
63720	Pediatric Universal set	63720	Sterile