

EU Declaration of Conformity

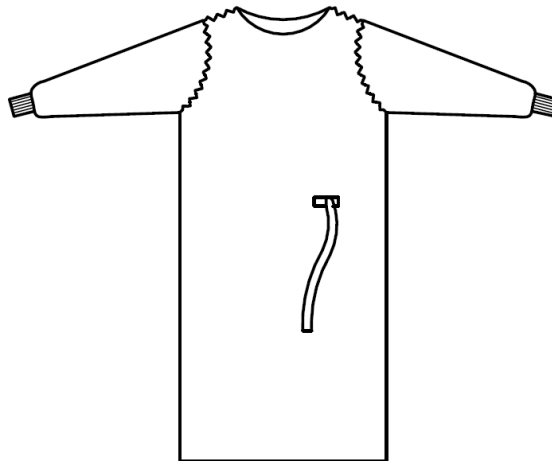
- 1. Product Name:** Surgical Gowns
Classification: Type PB4-B
Model: ZDB121012
Size: L, L-L, XL, XL-L, XXL-L, XXL-XL

- 2. Manufacturer:**
Name: Xuchang Zhengde Environstar Medical Products Co., Ltd.
Address: Area B, Baihua Road East, South Side of Erji river, Industry Cluster District, Yanling County, 461200 Xuchang, Henan, China

- 3. European Representative:**
Name: MedPath GmbH
Add: Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

- 4. Statement:**
We declare that the Surgical Gown is in the compliance with the Personal Protective Equipment Regulation (EU) 2016/425. The EU declaration of conformity is issued under the sole responsibility of Xuchang Zhengde Environstar Medical Products Co., Ltd.

- 5. Object of the declaration:**



- 6. Standard Applied:**

EN ISO 13485:2016	EN ISO13688:2013
EN14126:2003/AC:2004	EN 14605:2005 + A1:2009

- 7. Notified Body:**

Name: BSI Group The Netherlands B.V.
Address: Say Building, John M. Keynesplein 9, 1066 EP Amsterdam | P.O. Box 74103, 1070 BC Amsterdam The Netherlands
Identification number: 2797

- 8. Conformity Assessment Route:**

Based on the Annex V: EU type-examination (Module B) and Annex VIII: Conformity

ZZD/QSPPE-04

Xuchang Zhengde Environstar Medical Products Co., Ltd.

to type based on quality assurance of the production process (Module D).



9. (EC) Certificate(s) Number: The application is in process

Expire date of the certificate: The application in process

Date of issue the certificate: The application in process

Signed for and on behalf of Xuchang Zhengde Envirostar Medical Products Co., Ltd.:

Signature:

Place, date of issue:

Name: Chen Ming

Position: Regulatory Director