

## EU Declaration of Conformity

- 1. Product Name:** Surgical Gowns  
Classification: Type PB4-B  
Model: ZDB121020  
Brand: Barrier  
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

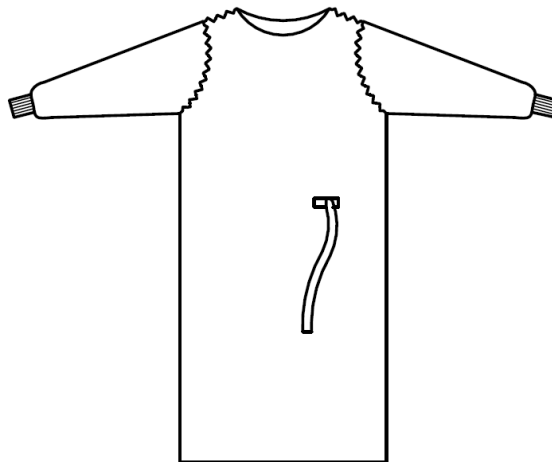
**3. European  
Representative:**

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:**

ZZD/QSPPE-04

Xuchang Zhengde Environstar Medical Products Co., Ltd.

Based on the Annex V: EU type-examination (Module B) and Annex VIII: Conformity 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 Environstar Medical Products Co., Ltd.:

Signature:

Place, date of issue:

Name: Chen Ming

Position: Regulatory Director