

## UK 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

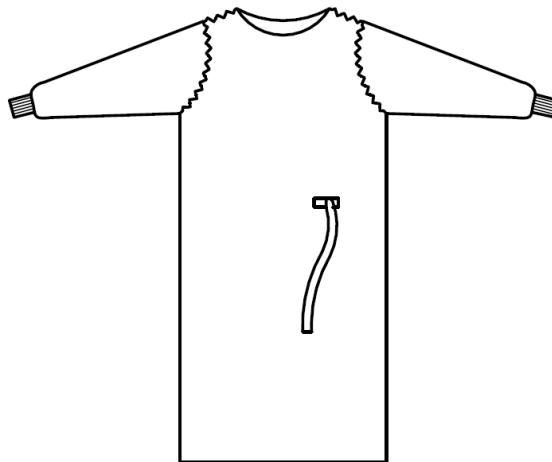
**2. Manufacturer:**

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. 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.

**4. Object of the declaration:**



**5. Standard Applied:**

EN ISO 13485:2016  
EN14126:2003/AC:2004

EN ISO13688:2013  
EN 14605:2005 + A1:2009

**6. Approved Body:**

Name: BSI Assurance UK Ltd  
Address: Kitemark Court, Davy Avenue, Milton Keynes, MK5 8PP, United Kingdom  
Identification number: 0086

**7. Conformity Assessment Route:**

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).

ZZD/QSPPE-04

Xuchang Zhengde Environstar Medical Products Co., Ltd.



**8. (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