

EU Declaration of Conformity

- 1. Product Name:** Surgical Gown VIRUS PROTECTION PLUS
Classification: Type PB[4]-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

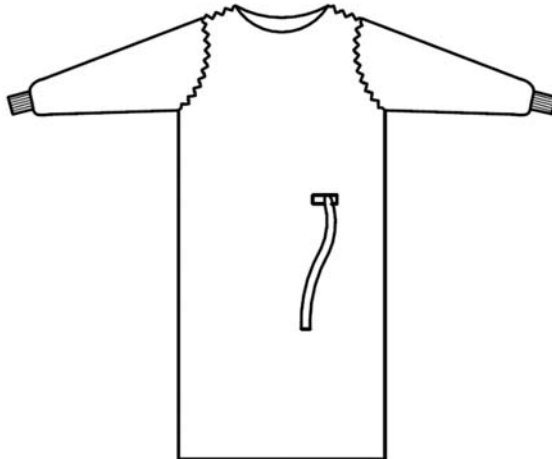
3. Authorised Representative:

Name: CMC Medical Devices & Drugs S.L.
Add: C/Horacio Lengo, 18, 29006, Málaga, Spain.

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 14605:2005 + A1:2009 EN14126:2003 EN ISO13688:2013

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:

Module B certificate: CE 729632

Module D certificate: CE 729633

Expire date of the certificate: 2026-05-26

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

Signature: 

Place, date of issue: Xuchang, 2024-02-26

Name: Chen Ming

Position: Regulatory Director