

EU Declaration of Conformity

- 1. Product Name:** Surgical Gown VIRUS PROTECTION PLUS
Classification: Category III, Type PB [4]-B
Model: ZDB121020
Brand: Barrier®
Size: L, L-L, XL, XL-L, XXL-L, XXL-XL
(For the product details please refer to attached the Product List)

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

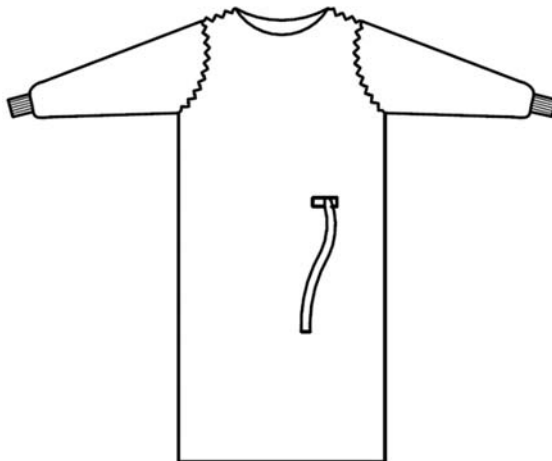
3. Authorised Representative:

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

ZZD/QSPPE-04-D016

Xuchang Zhengde Environstar Medical Products Co., Ltd.



8. Conformity Assessment Route:

Based on the Regulation (EU) 2016/425 on Personal Protective Equipment (PPE) Annex V: 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 777785

Module D certificate: CE 729633

Expiry date of the certificate:

2027-11-06 for CE 777785

2026-05-26 for CE 729633

Date of issue the certificate:

2022-11-07 for CE 777785

2022-09-06 for CE 729633

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

Signature:

A handwritten signature in black ink, appearing to be 'Chen Ming'.

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

Name: Chen Ming

Position: Regulatory Director



Product List

REF	Description	Sterility	UDI code
652400-00	Surgical Gown Virus Protection Plus (VPP) L	Sterile	6931747818235
652401-00	Surgical Gown Virus Protection Plus (VPP) L-L	Sterile	6931747818266
652402-00	Surgical Gown Virus Protection Plus (VPP) XL	Sterile	6931747818297
652403-00	Surgical Gown Virus Protection Plus (VPP) XL-L	Sterile	6931747818327
652404-00	Surgical Gown Virus Protection Plus (VPP) XXL-L	Sterile	6931747818358
652405-00	Surgical Gown Virus Protection Plus (VPP) XXL-XL	Sterile	6931747818389
752400-00	Surgical Gown Virus Protection Plus (VPP) L	Non Sterile	6931747818570
752401-00	Surgical Gown Virus Protection Plus (VPP) L-L	Non Sterile	6931747818587
752402-00	Surgical Gown Virus Protection Plus (VPP) XL	Non Sterile	6931747818594
752403-00	Surgical Gown Virus Protection Plus (VPP) XL-L	Non Sterile	6931747818600
752404-00	Surgical Gown Virus Protection Plus (VPP) XXL-L	Non Sterile	6931747818617
752405-00	Surgical Gown Virus Protection Plus (VPP) XXL-XL	Non Sterile	6931747818624