

EU DECLARATION OF CONFORMITY

No: DOC-ZD428D

1. PPE: Protective Coverall

Type: Category III Model: ZD428D Sizes: XS, S, M, L, XL, XXL

2. Manufacturer:

Name: Xuchang Zhengde Environstar Medical Products Co., Ltd.

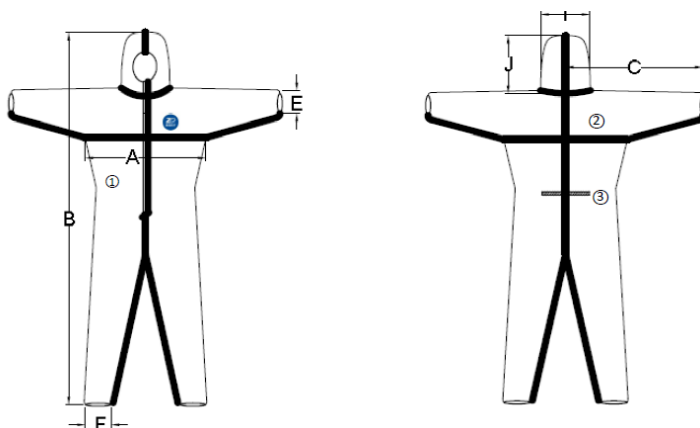
Address: Area B, Baihua Road East, South Side of Erji river, Industry Cluster District, Yanling County 461200 Xuchang City, Henan Province, China

Manufacturer Site II: No. 3, Weilai Road, Industry Cluster District, Yanling County 461200 Xuchang City, Henan Province, China

3. Statement:

We declare that the Protective Coverall is in the compliance with the Personal Protective Equipment Regulation (EU) 2016/425. This EU declaration of conformity is issued under the sole responsibility of Xuchang Zhengde Environstar Medical Products Co., Ltd.

4. Object of the declaration :



5. The object of the declaration described in point 4 is in conformity with the relevant Union harmonization legislation:

Regulation (EU) 2016/425

6. References to the relevant harmonized standards:

EN 14126:2003/AC:2004 Protective clothing — Performance requirements and tests methods for protective clothing against infective agents.

EN ISO13688:2013 Protective clothing — General requirements (ISO 13688:2013).

EN 14605:2005+A1:2009 Protective clothing against liquid chemicals - performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])

EN ISO 13982-1:2004/A1:2010 Protective clothing for use against solid particulates — Part 1: Performance requirements for chemical protective clothing providing protection to the full body against airborne solid particulates (type 5 clothing).

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EN 13034:2005+A1:2009 Protective clothing against liquid chemicals — Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment).

En 1149-5: Protective clothing-Electrostatic properties -Part 5: Material performance and design requirements


7. The notified body Universal (NB: 2163) performed the EU type-examination (Module B) and issued the EU type-examination certificate No.: 2163-PPE-2020

8. The PPE is subject to the conformity assessment procedure: Conformity to type based on internal production control plus supervised product checklist at random intervals (Module C2) under surveillance of the notified body Universal (NB: 2163). Module C2 certificate No.:2163-PPE-2020/01

10. Signed for and on behalf of:

Company: Xuchang Zhengde Environstar Medical Products Co., Ltd.

Regulatory Director: Chen Ming

Signature 



Place & Date: Xuchang, 16th August, 2021