

UKCA Declaration of Conformity

1. Product Name: Particulate Respirators

Model number: N9501Z Level: FFP2

2. Manufacturer:

Name: Xuchang Zhende Surgical Dressing Co., Ltd.

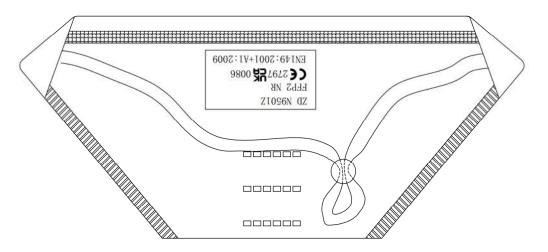
Address: No. 1 Jinhui Road, Industry Cluster District, Yanling County,

461200, Xuchang City, Henan Province, CHINA

3. Statement:

We declare that the Particulate Respirators FFP2 is in the compliance with the PPE Regulation EU 2016/425 on personal protective equipment as brought into UK law and amended. The UKCA declaration of conformity is issued under the sole responsibility of Xuchang Zhende Surgical Dressing Co., Ltd.

4. Object of the declaration:



5. Standard Applied:

EN ISO 13485:2016 EN 149:2001+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 the Annex VIII: Conformity to type based on quality assurance of the production process (Module D).

8. Certificate(s) Number : UKCA 748668(B certificate) UKCA 748669(D certificate)

Expire date of the certificate: 2026-12-07

Place, Issue date of the certificate: Xuchang, 2021-12-07

Place and Date of Issue the DOC: Xuchang, 2021-12-15

Signed for and on behalf of Xuchang Zhende Surgical Dressing Co., Ltd.

Signature:

Name: Chen Ming

Position: Regulatory Director