Xuchang Zhende Surgical Dressing Co., Ltd.



# **UKCA Declaration of Conformity**

1. Product Name: Particulate Respirators

Model number: N9901Z Level: FFP3

2. Manufacturer:

Name: Xuchang Zhende Surgical Dressing Co., Ltd.

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

Version:

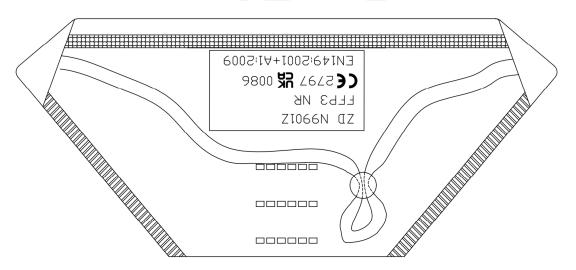
Status: 0

461200, Xuchang City, Henan Province, CHINA

### 3. Statement:

We declare that the Particulate Respirators FFP3 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).

Version: A

Status: 0

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