# Xuchang Zhende Surgical Dressing Co., Ltd.



## **EU 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,

Version:

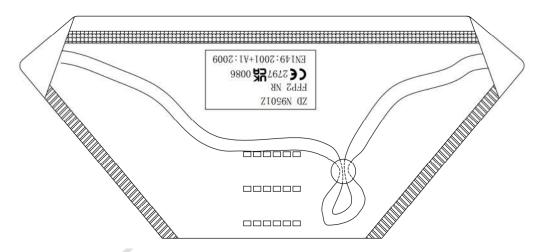
Status: 0

461200, Xuchang City, Henan Province, CHINA

#### 3. Statement:

We declare that the Particulate Respirators FFP2 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 Zhende Surgical Dressing Co., Ltd.

#### 4. Object of the declaration:



### 5. Standard Applied:

EN ISO 13485:2016 EN 149:2001+A1:2009

6. 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



Name: BSI Assurance UK Ltd

Address: Kitemark Court, Davy Avenue, Milton Keynes, MK5 8PP

Version:

Status: 0

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. (EC) Certificate(s) Number : The application is in process

Expire date of the certificate: The application is in process

Place, Issue date of the certificate: The application is in process

Place and Date of Issue the DOC: The application is in process

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

Signature:

Name: Chen Ming

Position: Regulatory Director