



## EU Declaration of Conformity

**1. Product Name:** Particulate Respirators

Model number: N9501F    Level: FFP2

**2. Manufacturer:**

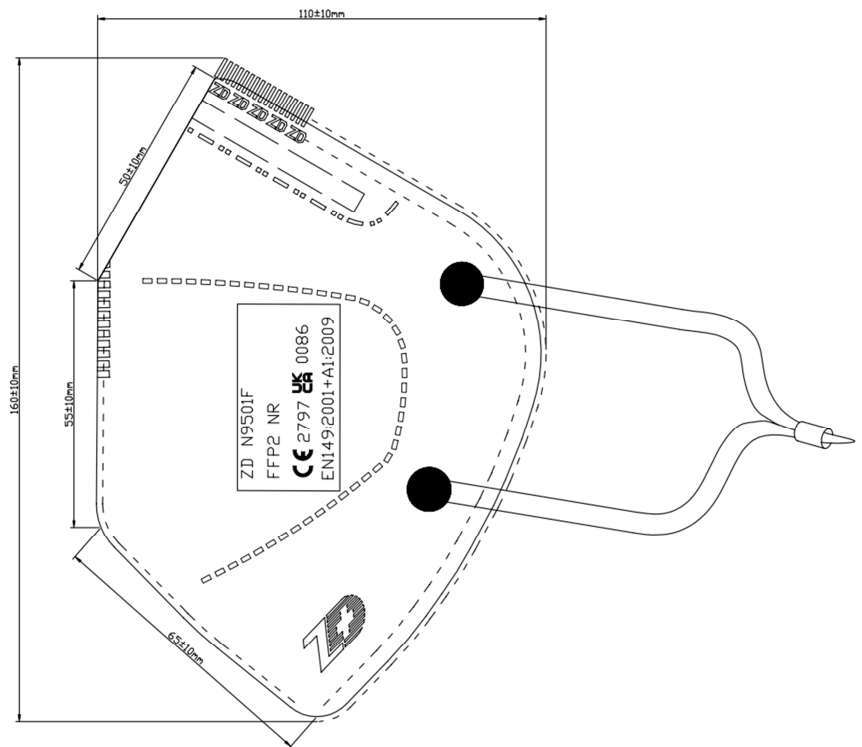
Name: Xuchang Zhende Surgical Dressing Co., Ltd.

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 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

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