



## EU Declaration of Conformity

1. **Product Name:** Particulate Respirators FFP2 NR  
Model number: N9501Z

2. **Manufacturer:**

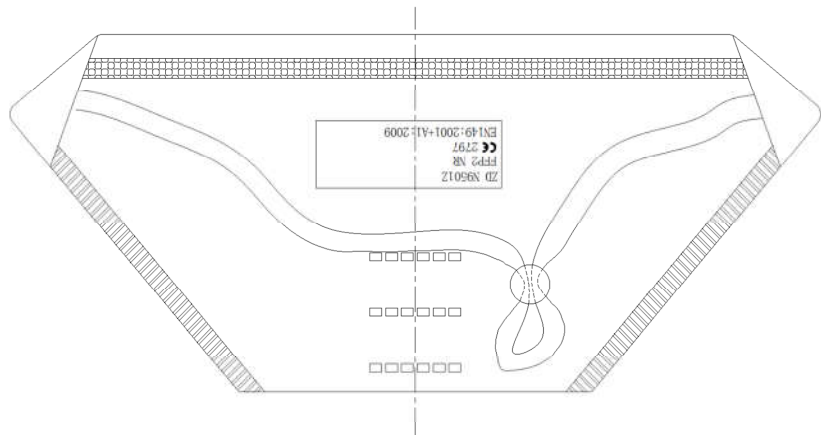
Name: Zhende Medical Co., Ltd.

Address: Gaobu Town, 312035, Shaoxing, Zhejiang, PEOPLE'S  
REPUBLIC OF 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 Zhende Medical Co., Ltd.

4. **Object of the declaration:**



5. **Standard Applied:**

EN ISO 9001:2015 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

7. **Conformity Assessment Route:**

Based on the Annex V: EU type-examination (Module B) and the Annex VII: Conformity to type based on internal production control plus supervised product checks at random intervals (Module C2).

8. **(EC) Certificate(s) Number : TO BE APPLIED FOR**


**Expire date of the certificate: TO BE APPLIED FOR**

**Place, Issue date of the certificate: TO BE APPLIED FOR**



Place and Date of Issue the DOC: Shaoxing, Zhejiang, China. 2021.02.20

Signed for and on behalf of **Zhende Medical Co., Ltd.**

Signature: 

Name: Chen Ming

Position: Regulatory Director