

Declaration of Conformity

1. **Product Name:** Particulate Respirators FFP2 NR
Model number: N9501F

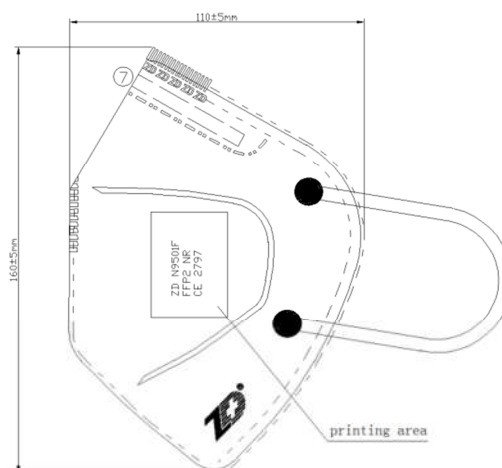
2. **Manufacturer:**

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

Technical specification to satisfy Annex II of the PPE Regulation (EU) 2016/425. BSI's PPE for Healthcare Professionals 2020/403 – RPE Technical Specification.

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):**

Place and Date of Issue: Shaoxing, Zhejiang, China. 2020.4.22

Signature: 

Name: Chen Ming

Position: Quality Director