



EU Declaration of Conformity

1. **Product Name:** Particulate Respirators FFP2 NR
Model number: N9501T

2. **Manufacturer:**

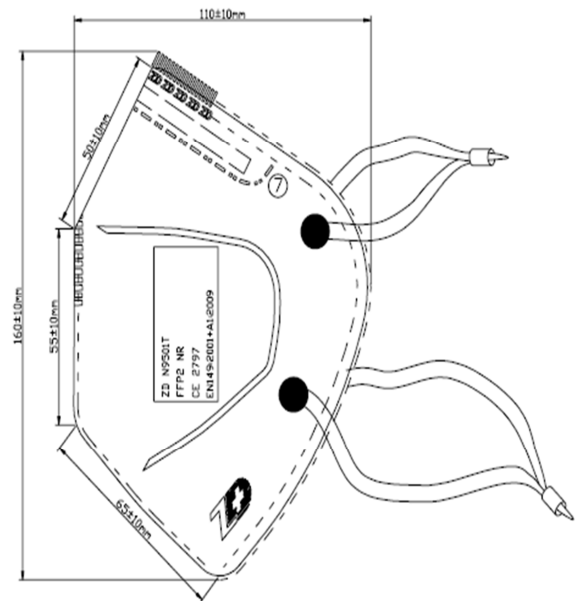
Name: Zhende Medical Co., Ltd.

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 :** CE 727499 & CE 727500


Expire date of the certificate: 2026-04-14

Place, Issue date of the certificate: Shaoxing, 2021-09-27



Place and Date of Issue the DOC: Shaoxing, Zhejiang, China. 2021-09-28

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

Signature: 

Name: Chen Ming

Position: Regulatory Director