ZDYL/QSPPE-01 Zhende Medical Co., Ltd.



EU Declaration of Conformity

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

2. Manufacturer:

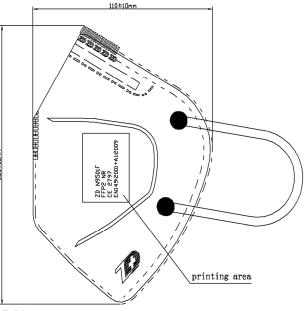
Name: Zhende Medical Co., Ltd. Address: Gaobu Town, 312035, Shaoxing, Zhejiang, PEOPLE'S

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 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: 2021-04-14

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Version: A Status: 0



Place and Date of Issue the DOC: Shaoxing, Zhejiang, China. 2021-04-17

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

Signature:

Name: Chen Ming

Position: Regulatory Director