

# **EU Declaration of Conformity**

1. Product Name: Particulate Respirators

Model number: N9501T Level: FFP2

#### 2. Manufacturer:

Name: Xuchang Zhende Surgical Dressing Co., Ltd.

Address: No. 1 Jinhui Road, Industry Cluster District, Yanling County,

Version:

Status: 0

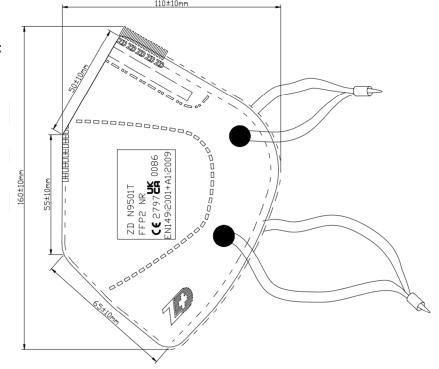
461200, Xuchang City, Henan Province, CHINA

#### 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

# 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 : CE 748666 (B certificate) CE 748667 (D certificate)

Expire date of the certificate: 2026-12-07

Place, Issue date of the certificate: Xuchang, 2021-12-07

Place and Date of Issue the DOC: Xuchang, 2021-12-15

Signed for and on behalf of Xuchang Zhende Surgical Dressing Co., Ltd.

Signature:

Name: Chen Ming

Position: Regulatory Director