

## EU Declaration of Conformity

No: DOC-ZD001

1. PPE: Filtering half mask

Type: Category III Model number: ZD-001 Level: FFP2

2. Manufacturer:

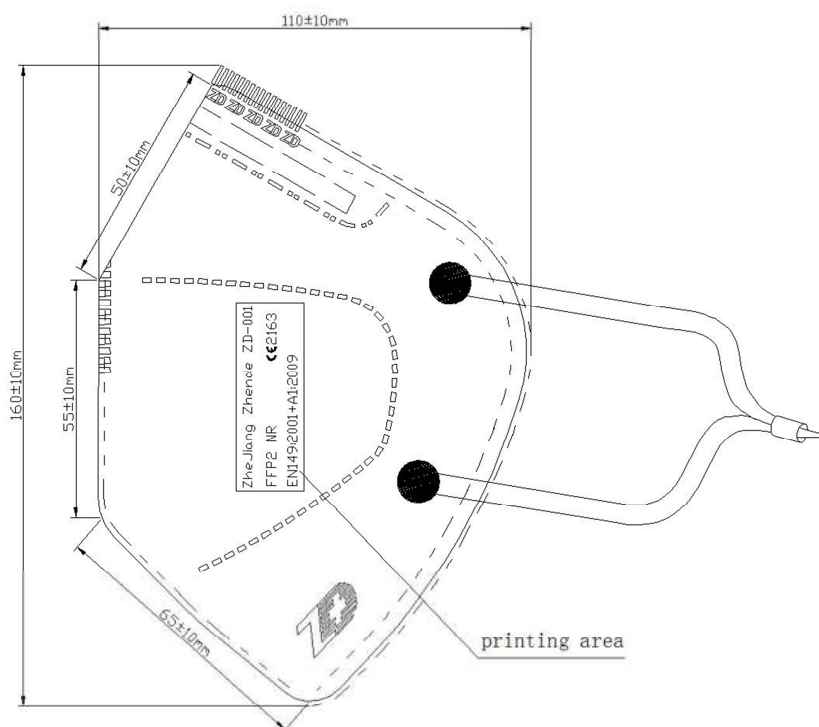
Name: Zhende Medical Co., Ltd.

Address: Gaobu Town, 312035, Shaoxing City, Zhejiang Province, China

3. Statement:

We declare that the filtering half mask 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. The object of the declaration described in point 4 is in conformity with the relevant Union harmonisation legislation:

Regulation (EU) 2016/425

6. References to the relevant harmonised standards:

EN 149:2001+A1:2009 ISO 9001:2015

7. The notified body Universal (NB: 2163, address: Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:44/84 Yukarı Dudullu Ümraniye/İSTANBUL – TURKEY) performed the EU

振德医疗用品股份有限公司  
Zhende Medical Co., Ltd.

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type-examination (Module B) and issued the EU type-examination certificate:  
2163-PPE-1248

8. The PPE is subject to the conformity assessment procedure: Conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) under surveillance of the notified body Universal (NB: 2163). And the number of the certificate of Module C2 is 2163-PPE-1248/01

9. Signed for and on behalf of:

Company: Zhende Medical Co., Ltd.

Regulatory Director: Chen Ming

Place & Date: Shaoxing, 20<sup>th</sup> August, 2020

Signature:

