

**CERTIFICATE OF CONFORMANCE****Certificate No: 2163-PPE-1248/01**

Respiratory protective devices, filtering half masks to protect against particles manufactured by

**Zhende Medical Co., Ltd.**

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

Continues to fulfil the requirements of

**EN 149:2001 + A1:2009 Respiratory Protective Devices -  
Filtering Half Masks to Protect Against Particles -  
Requirements, Testing, Marking**

Based on the evaluation of test reports and internal quality control audit reports according to EN 149+A1:2009 and Personal Protective Equipment Regulation (EU) 2016/425 Annex VII (Module C2). This certificate implies that the manufactured products show below are in conformance with the approved EU Type Examination model and meets the requirements of the regulation.

**Product Definition**

Model	Class	EU Type Examination Certificate		
		Serial No	Date	Issuing NB No
ZD / ZD-001	FFP2 NR	2163-PPE-744	09.08.2020	2163

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9**.
- Taking all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type examination certificate.

This certificate is issued on **09/08/2020** and will be valid for one year, until **08/08/2021** if the manufacturer makes no major change in the product designs and manufacturing processes affecting the product performance on the essential health and safety requirement.



Suat KAÇMAZ  
UNIVERSAL CERTIFICATION  
Director





## EU Declaration of Conformity

No: DOC-ZD001

1. PPE: Filtering half mask

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

2. Manufacturer:

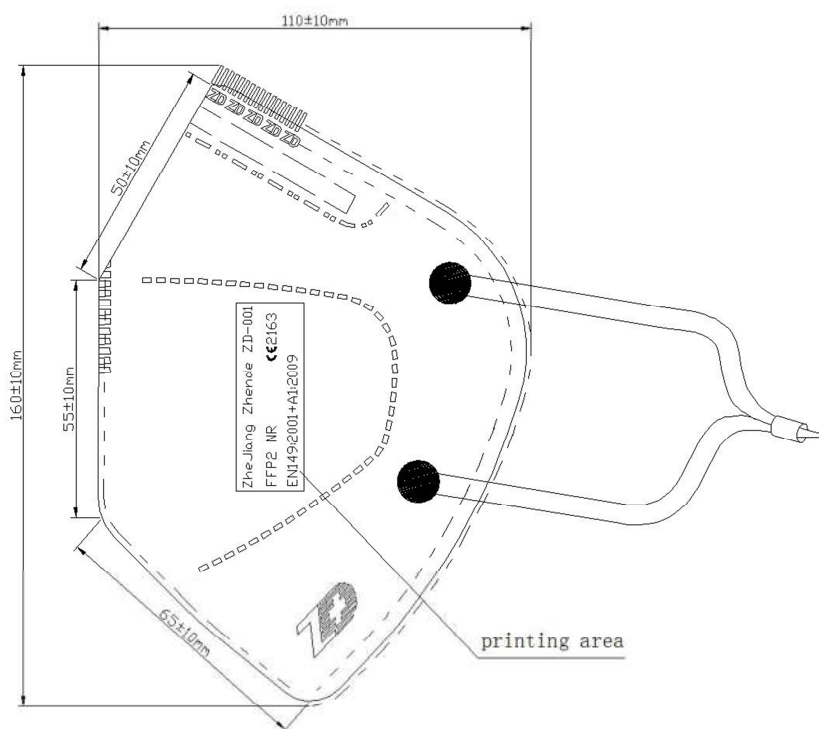
Name: Zhende Medical Co., Ltd.

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:

