



UNIVERSAL  
CERTIFICATION

NB 2163

## EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1248

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

**Zhende Medical Co., Ltd.**

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

are tested and evaluated according to

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

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation.

#### **Product Definition**

**Brand Name:** ZD **Model:** ZD-001

Filtering half mask

**Classification:** FFP2 NR

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**.
- Ongoing successful performance in fulfilment of the requirements set out in Personal Protective **Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation no later than 1 year from the beginning of serial production

This certificate is initially issued on **09/08/2020** and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.



Suat KAÇMAZ  
UNIVERSAL CERTIFICATION  
Director

