

EU Declaration of Conformity

No: DOC-ZD001

1. PPE: Filtering half mask

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

2. Manufacturer:

Name: Zhende Medical Co., Ltd.

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

EC-Representative:

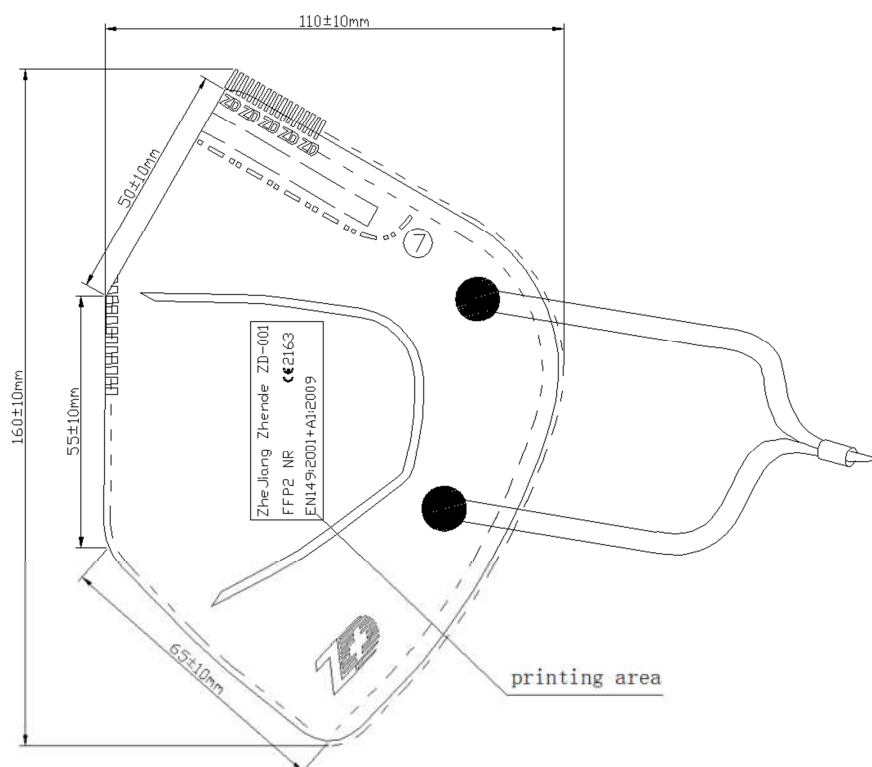
Name: M/s AOC Consulting.

Address: Jiráskova 599, CZ-432 01Kadaň, Czech

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

7. The notified body Universal (NB: 2163, address: Tatlısu Mah. Arif Ay Sk. No:16-3 Umraniye-Istanbul /TURKEY) performed the EU 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, 2021-05-19

Signature:

