振德医疗用品股份有限公司
Zhende Medical Co., Ltd.

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

   Authorised representative:

   Name: AOC Consulting

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

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:
   Filtering half mask, FFP2

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/N1

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/N1/01

9. Signed for and on behalf of:

Company: Zhende Medical Co., Ltd.

Regulatory Director: Chen Ming

Place & Date: Shaoxing, 2025-04-30

Signature: