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CERTIFICATION

NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-950

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

Zhejiang Gen Yuan Tang Medical Technology Co., Ltd.
No.1278-1308 Wanxiang Road, Wanquan Town, Pingyang County, Wenzhou City, Zhejiang, 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

Model: FQ66
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 **06/07/2020** and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code

Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:44/84 Yukarı Dudullu Ümraniye - İSTANBUL - TURKEY T:+90 216 455 80 80
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NB 2163

CERTIFICATE OF CONFORMANCE

Certificate No: 2163-PPE-950/01

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

Zhejiang Gen Yuan Tang Medical Technology Co., Ltd.
No.1278-1308 Wanxiang Road, Wanquan Town, Pingyang County, Wenzhou City, Zhejiang, 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
FQ66	FFP2 NR	2163-PPE-950	06.07.2020	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 **06/07/2020** and will be valid for one year, until **05/07/2021** 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.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code

EU DECLARATION OF CONFORMITY

DOC No:

1. PPE : FQ66, FFP2 facemask

2. Name and address of the manufacturer:

Zhejiang Gen Yuan Tang Medical Technology Co.,Ltd , add: No.1278-1308 Wanxiang Road,Wanquan Town, Pingyang County,Wenzhou City,Zhejiang,China.

3.This declaration of conformity is issued under the sole responsibility of the manufacturer.

4. Object of the declaration : FFP2 facemask

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 Respiratory protective devices – Filtering half masks to protect against particles – Requirements, testing, marking.

7. The notified body **Universal** (NB: 2163) performed the EU type-examination (Module B) and issued the EU type-examination certificate: 2163-PPE-950

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).

9. Signed for and on behalf of:

Company: Zhejiang Gen Yuan Tang Medical Technology Co.,Ltd.

General Manager: Fang Fang Fang

Signature: Fang Fang Fang

Place & Date: Wenzhou 12.14. 2020

CE