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UNIVERSAL

CERTIFICATION

NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1278/R1

Respiratory protective devices, filtering half masks to protect against particles manufactured by **Zhejiang Shaohua Medical Equipment Co., Ltd.**

Floor 1, Building 6, Block A, No. E22, Xinke Road, Choujiang Street, Yiwu 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

Single shift use particle filtering half mask for protection against solid and liquid aerosols, is a folding type, 5 layers, without valve, built-in nose clip and sponge strip, fitted with ear loops and ear strap clasp buckle.

Brand Name: YWSH **Model:** SH-ZK12

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 **15/08/2020** and updated on **07/04/2021** will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.

YWSH®

Import:

Quantity:

Date stamped:



Suat KAÇMAZ

UNIVERSAL CERTIFICATION

Director



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CERTIFICATION

NB 2163

CONFORMITY TO TYPE CERTIFICATE

Certificate No: 2163-PPE-1278/02

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

Zhejiang Shaohua Medical Equipment Co., Ltd.

Floor 1, Building 6, Block A, No. E22, Xinke Road, Choujiang Street, Yiwu 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

Table with 5 columns: Model, Class, EU Type Examination Certificate (Serial No, Date, Issuing NB No). Row 1: YWSH / SH-ZK12, FFP2-NR, 2163-PPE-1278/R1, 07.04.2021, 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 07/04/2021 and will be valid for one year, until 06/04/2022 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.

YWSH®

Import:
Quantity:
Date stamped:



Handwritten signature of Suat KACMAZ

Suat KACMAZ
UNIVERSAL CERTIFICATION
Director

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