

**NB 2163** 

# EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163 - PPE - 667

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

#### **DISTRIBUZIONE JUNIOR SRL**

Via Pace, 25/26 - 80047 San Giuseppe Vesuviano (Na) ITALY manufactured at

#### MEIZHUANGCHEN HEALTH TECHNOLOGY (SHENZHEN) CO., LTD

Meizhuangchen Health Technology (Shenzhen) Co. Ltd No.12, Yuhe Road, Shiyan Town, Baoan District, Shenzhen, 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**

Branda: ENHANCE Model: ENKN95-001 Filtering half mask Total Inwards Leakage: Class - FFP2

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 08 / 05 /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 KACMAZ UNIVERSAL CERTIFICATION Director



NB 2163

# CERTIFICATE OF CONFORMANCE

Certificate Nr: 2163 - PPE - 667/01

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### MEIZHUANGCHEN HEALTH TECHNOLOGY (SHENZHEN) CO., LTD

Meizhuangchen Health Technology (Shenzhen) Co. Ltd No.12, Yuhe Road, Shiyan Town, Baoan District, Shenzhen, 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 Nr.	Date	Issuing NB Nr.
ENKN95-001	FFP2	2163-PPE-667	08.05.2020	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 08/05/2020 and will be valid for one year, until 07/05/2021 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.



Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director