UNIVERSAL

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CERTIFICATION

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.

CE
2163

Sunt KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR

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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CERTIFICATION

NB 2163

CERTIFICATE OF CONFORMANCE

Certificate Nr: 2163 - PPE – 667/01

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.

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.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR

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CERTIFICATION OF REGISTRATION

This certifies that:
Mezorrison Health Science &Technology(Shenzhen) Co., Ltd
No.12 Yuhe Road, Shiyan Town, Bao'an District, Shenzhen, Guangdong, 518000, CHINA

is registered and has listed the following medical device with the U.S. Food and Drug Administration :

Owner/Operator Number : 10064314

Listing Number: D378809

Product Code : MSH

Product : Respirator filter

Model(s) : MZC-KZ-06

Date Of Registration Status: 2020

Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holderd's device or establishment by the U.S. Food and Drug Administration. Registrar Corp assumes no liability to any person or entity in connection with the foregoing.
Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."
The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Registrar Corp is not affiliated with the U.S. Food and Drug Administration

Chief Engineer: Zaochao Lee

Issued: Mar. 25, 2020
Validity Period:2020-12-31

Web rep/www.fda.gov Tel 1-888-INFO-FDA(1-888-0332) E-mal vcrp@fda.gov