

# EU TYPE EXAMINATION CERTIFICATE

***THIS IS TO CERTIFY*** that KR Hellas Ltd., designated by the Hellenic Republic of Greece as Notified Body under the terms of Personal Protective Equipment Regulation (EU) 2016/425, did undertake the EU Type Examination procedures for the equipment identified below which was found to be in compliance with relevant provisions of Regulation (EU) 2016/425, or as amended, subject to any conditions in the schedule attached hereto.

**Manufacturer**                      **Name**     :  **YIWU WEI KANG MEDICAL INSTRUMENTS CO.,LTD**  
**Address**         :  **No.2288 The South of Hehua, Chou Jiang Street, Yiwu City, Zhejiang Province, China**

**Equipment**                             :  **Filtering half mask**

**Model name**                           :  **CPT**

**Harmonised Standard(s)**           :  **EN 149:2001+A1:2009**

This equipment complies with Essential Health and Safety Requirements of Annex II to the Regulation (EU) 2016/425. The examination and test results are recorded in the assessment report KRH-PPE-0064-2020. This EU-Type Examination Certificate relates only to the design, examination and tests of the specified personal protective equipment in accordance to Regulation (EU) 2016/425. Further requirements of the Regulation apply to the manufacturing process and supply of this personal protective equipment. These are not covered by this certificate.

This certificate is issued at Athens on 4<sup>th</sup> September 2020, under the authority of the Hellenic Republic of Greece by KR Hellas Ltd., Notified Body No. 2198.

Notified Body No.2198



**Dr. Nikos Katiforis**  
**Quality manager**  
**of KR Hellas Ltd.**

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(Form PPE-EC, Rev.0, 2017.04.01)(Page 1/2)

## Schedule of Approval (1/1)

### **Equipment Description:**

1. This equipment is particle filtering half mask.
2. This particle filtering half masks are classified as FFP2 and single shift use only.
3. Classification: FFP2 NR

### **Limitations of Use:**

1. Usage, maintenance and storage as per manufacturer's instructions.

### **Test and assessment report:**

1. KRH-PPE-0064-2020

### **Conditions of the validity:**

1. This certificate shall only be used in conjunction with one of the conformity assessment procedures referred to in point (c) of Article 19 of the Regulation (EU) 2016/425.
2. When applying the Mark of Conformity (the "CE" mark) to the equipment that conform to the type examined, the manufacturer of this equipment is obliged to add, the identification number of the Notified Body engaged in assessment referred to in point (c).(i) or (c).(ii) of Article 19 and set out in Annex VII or VIII correspondingly of the Regulation (EU) 2016/425.
3. If the applied standard(s) is amended, the equipment is to be re-approved in accordance with the amended requirements prior to its being placing on the market to which the amended standard(s) apply. Any significant changes in design or construction of the equipment, or amendments to the standards referenced above may render this certificate invalid.
4. The manufacturer must inform the Notified Body of all modifications which may affect compliance with the requirements.

### **Remark:**

1. Initial issued on 4<sup>th</sup> September 2020.

*End of Certificate*