

**EU Declaration of Conformity**  
**Annex IX PPE Regulation (EU) 2016/425**

This EU Declaration of conformity refers to the following products:

1. Product info

Name: Particle filtering half mask

Model: HK-Z03

Classification: FFP2 NR

2. The Manufacturer's name and address is as follows:

Name: Changzhou Huankang Medical Device Co., Ltd.

Address: No.22, Changhe Road, Zhenglu Town, Tianning District, Changzhou City, Jiangsu, China

3. This Declaration of Conformity is issued under the sole responsibility of the Manufacturer.

4. Detailed description of the PPE to allow traceability/identification of the PPE.

HK-Z03



The article identified in (4) above is in conformance with the relevant Union Harmonization Legislation Regulation (EU) 2016/425.

References to the relevant harmonized standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:

**EN 149:2001+A1:2009**

CCQS Certification Services Limited. (NB 2834) performed the EU Type Examination (Module B) and issued the Type Examination Certificate Number: Module B

No.	EU Type Examination (Module B) Certificate Number
1	CE-PC-200722-565-01-9A

Product Category:

☒ This product is Category III and is subject to Module C2 internal production control plus supervised product checks at random intervals and is under the surveillance of CCQS Certification Services Limited. (NB 2834)

☐ This product is Category III and is subject to Module D Conformity to type based on quality assurance of the production process and is under the surveillance of CCQS Certification Services Limited. (NB 2834)

Signature: Cailong Zhai Date: 12.20.2020

Company stamp and/or legal signature: \_\_\_\_\_

常州市环康医疗器械有限公司  
CHANGZHOU HUANKANG MEDICAL DEVICE Co.,LTD

A handwritten signature in red ink, appearing to be '陈才龙' (Chen Cailong), written over the company stamp.

# Particle Filtering Half Mask

Classification: FFP2 NR

Standard: EN 149:2001+A1:2009

Model: HK-Z03

# CE 2834

## Warnings

1. This mask marked "NR", shall not be used for more than one shift.
2. Never substitute, modify, add, or omit parts in the configuration as specified by the manufacturer.
3. This mask offers protection against certain particulate contaminants but does not completely eliminate exposure to the risk of contracting disease or infection.
4. Do not use the particle half mask with facial hair or any other conditions that may prevent a good face-seal, the requirements of leakage will not be achieved.
5. Discard and replace the mask if:
  - a) The mask is removed whilst in the contaminated areas.
  - b) Clogging of the mask causes breathing difficulties.
  - c) The mask becomes damaged.

## Limitation

Do not use the respirator to enter or stay in a contaminated area under the following circumstances:

- 1) Atmosphere contains less than 19.5% oxygen.
- 2) If you smell or taste contaminant.
- 3) For protection against gases or vapors.
- 4) Contaminants or their concentrations are unknown or immediately dangerous to life or health.
- 5) For sandblasting, paint-spray operations and asbestos treatment.
- 6) In explosive atmospheres.

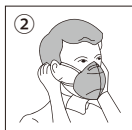
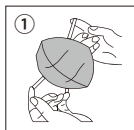
## Storage

The mask should not be removed from its package until it is required for use, and should be discarded after use.

## User Instruction

1. To protect your health and to prevent serious injury or death, it is important to read and follow all the instructions provided with the enclosed product. Please read all warning printed on the packaging box.
2. Please check prior to using to ensure: the head harness is attached well; the nose clip is attached properly on the mask.
3. This mask must only be used with the clip in place.

## Wearing&Fitting Instruction



1. Hold the particle filtering half mask firmly.
2. Place under chin and press the mask freely against your face with the nose clip on the bridge of your nose. Pull the head harness behind the ears.
3. Using both hands, mold the nose clip to the shape of nose.
4. To check for proper fit, cup both hands over the mask and exhale vigorously. If air leaks around the nose, tighten the nose clip, if air leaks around the edge, reposition the head harness for better fit.
5. Repeat adjustments until the mask is sealed properly.

## Manufacturer Info

Changzhou Huankang Medical Device Co., Ltd.

Address: No.22, Changhe Road, Zhenglu Town, Tianning District, Changzhou City, Jiangsu, China

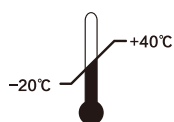
Telephone: +86-519-88909800

Post code: 213115

## Notified Body Info

CCQS Certification Services Limited

Address: Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown,  
Dublin15, D15 AKK1, Ireland (NB 2834)



temperature range of storage conditions



Maximum relative humidity of storage conditions



See information supplied by the manufacturer