



UNIVERSAL

CERTIFICATION

NB 2163

## EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1949

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

**Zhejiang Yiju Medical Instrument Co., Ltd.**

Songqiao Industrial Zone, Wanquan Town, Pingyang County, Wenzhou, Zhejiang, 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, fitted with ear loops, nose clip and internal sponge.

**Model: YJ20-02****Classification: FFP2 NR**

For more details, refer technical evaluation report provided to the manufacturer, dated 25.01.2021 and number 2163-KKD-1949

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.

This certificate is initially issued on **25/01/2021** 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 KAÇMAZ  
UNIVERSAL CERTIFICATION  
Director



## EU Declaration of Conformity

Annex IX PPE Regulation (EU) 2016/425

This EU Declaration of conformity refers to the following products

Product Name	Model	Classification/Type	Batch No./Serial No./Identifier
Filtering half mask	YJ20-02	FFP2 NR	20210120

The Manufacturer's name and address is as follows:

Name:	Zhejiang Yiju Medical Instrument Co., Ltd.
Address:	Songqiao Industrial Zone, Wanquan Town, Pingyang County, Wenzhou, Zhejiang, China

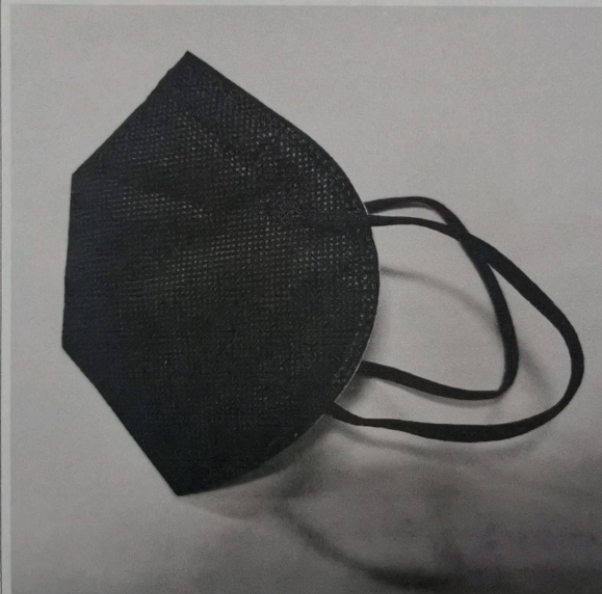
This Declaration of Conformity is issued under the sole responsibility of the Manufacturer.

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

Model: YJ20-02

FFP2 NR

Black folder half mask without valve



The article identified in product category 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:

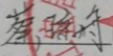
No.	Harmonized standard name
1	EN 149:2001+A1:2009

UNIVERSAL CERTIFICATION and SURVEILLANCE SERVICES Trade Co. (NB 2764) performed the EU Type Examination (Module B) and issued the Type Examination Certificate Number:

No.	EU Type Examination (Module B) Certificate Number
1	2163-PPE-3886

Product Category:

- This product is Category II.
- 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 UNIVERSAL CERTIFICATION and SURVEILLANCE SERVICES Trade Co. (NB 2764)
- 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 UNIVERSAL CERTIFICATION and SURVEILLANCE SERVICES Trade Co. (NB 2764)

Signature:  Date: 2021年5月14日 Company  
stamp and/or legal signature: \_\_\_\_\_

