Filtering Facepiece Respirators KN95/ FFP2

Australian Register of Therapeutic Goods (ARTG) 341459

Medical Device Included Class 1
Public respirator, single-use

Australian Register of Therapeutic Goods Certificate

Australian Government
Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

ARMIS INDUSTRIES PTY LTD

for approval to supply

ARMIS INDUSTRIES PTY LTD - Public respirator, single-use

ARTG Identifier	341459
ARTG Start Date	13/08/2020
Product Category	Medical Device Included Class 1
GMDN	57793
GMDN Term	Public respirator, single-use
Intended Purpose	A form-shaped filtering mask designed to be placed over the nose and mouth of a member of the general public to permit normal breathing while protecting the wearer from large particles (e.g., blood, body fluids, and airborne particulate materials) and small particles (e.g., bacteria and viruses) when considered necessary (e.g., viral epidemic). It is typically made of multiple layers of non-woven polymers to produce a soft, flexible mask that will create an airtight seal against the user's face and typically secured using elastic head straps or ties; it may incorporate a forming nosepiece (metal wire) and/or an exhalation valve. This is a single-use device.

Manufacturer Details	Address	Certificate number(s)
ZI GONG WEIKANG MEDICAL EQUIPMENT CO LTD	C2-07ab Hao Jiaba Industrial Park Xuyang Town Rong County ,;Sichuan Province ,; China	

ARTG Standard Conditions

The above Medical Device Included Class 1 has been entered on the Register subject to the following conditions:

- - The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- - Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Products Covered by This Entry

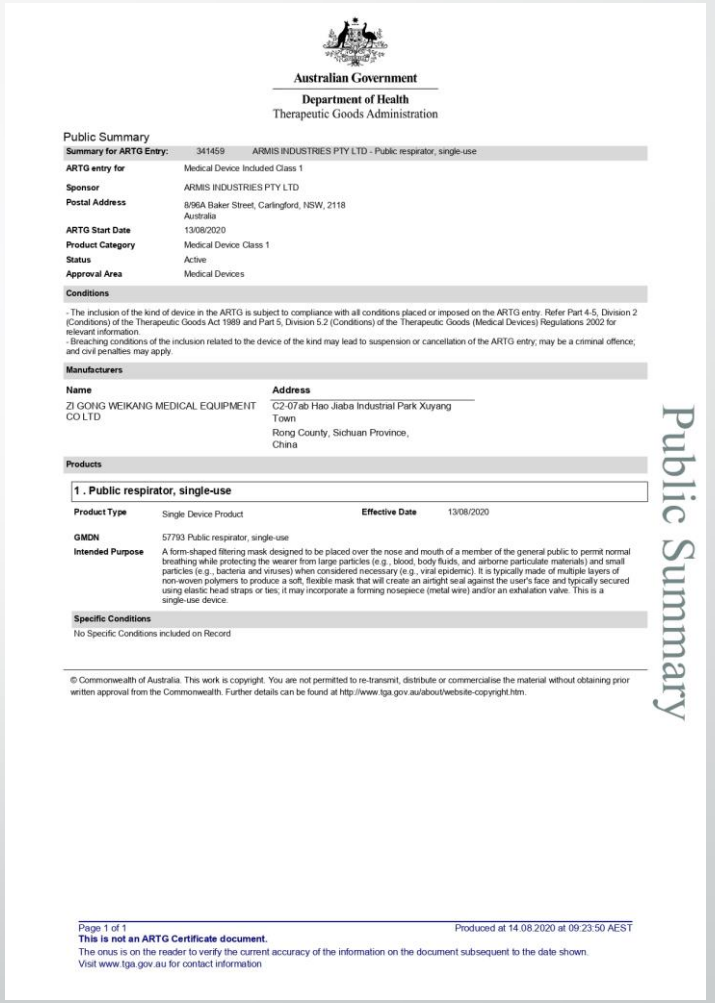
1. Public respirator, single-use

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653
Email: info@tga.gov.au

ARTG Identifier: 341459
ARTG Start Date: 13/08/2020



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	341459 ARMIS INDUSTRIES PTY LTD - Public respirator, single-use
ARTG entry for	Medical Device Included Class 1
Sponsor	ARMIS INDUSTRIES PTY LTD
Postal Address	8/96A Baker Street, Carlingford, NSW, 2118 Australia
ARTG Start Date	13/08/2020
Product Category	Medical Device Class 1
Status	Active
Approval Area	Medical Devices

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry, may be a criminal offence; and civil penalties may apply.

Manufacturers

Name	Address
ZI GONG WEIKANG MEDICAL EQUIPMENT CO LTD	C2-07ab Hao Jiaba Industrial Park Xuyang Town Rong County, Sichuan Province, China

Products

1 . Public respirator, single-use

Product Type	Single Device Product	**Effective Date**	13/08/2020
GMDN	57793 Public respirator, single-use		
Intended Purpose	A form-shaped filtering mask designed to be placed over the nose and mouth of a member of the general public to permit normal breathing while protecting the wearer from large particles (e.g., blood, body fluids, and airborne particulate materials) and small particles (e.g., bacteria and viruses) when considered necessary (e.g., viral epidemic). It is typically made of multiple layers of non-woven polymers to produce a soft, flexible mask that will create an airtight seal against the user's face and typically secured using elastic head straps or ties; it may incorporate a forming nosepiece (metal wire) and/or an exhalation valve. This is a single-use device.		

Specific Conditions

No Specific Conditions included on Record

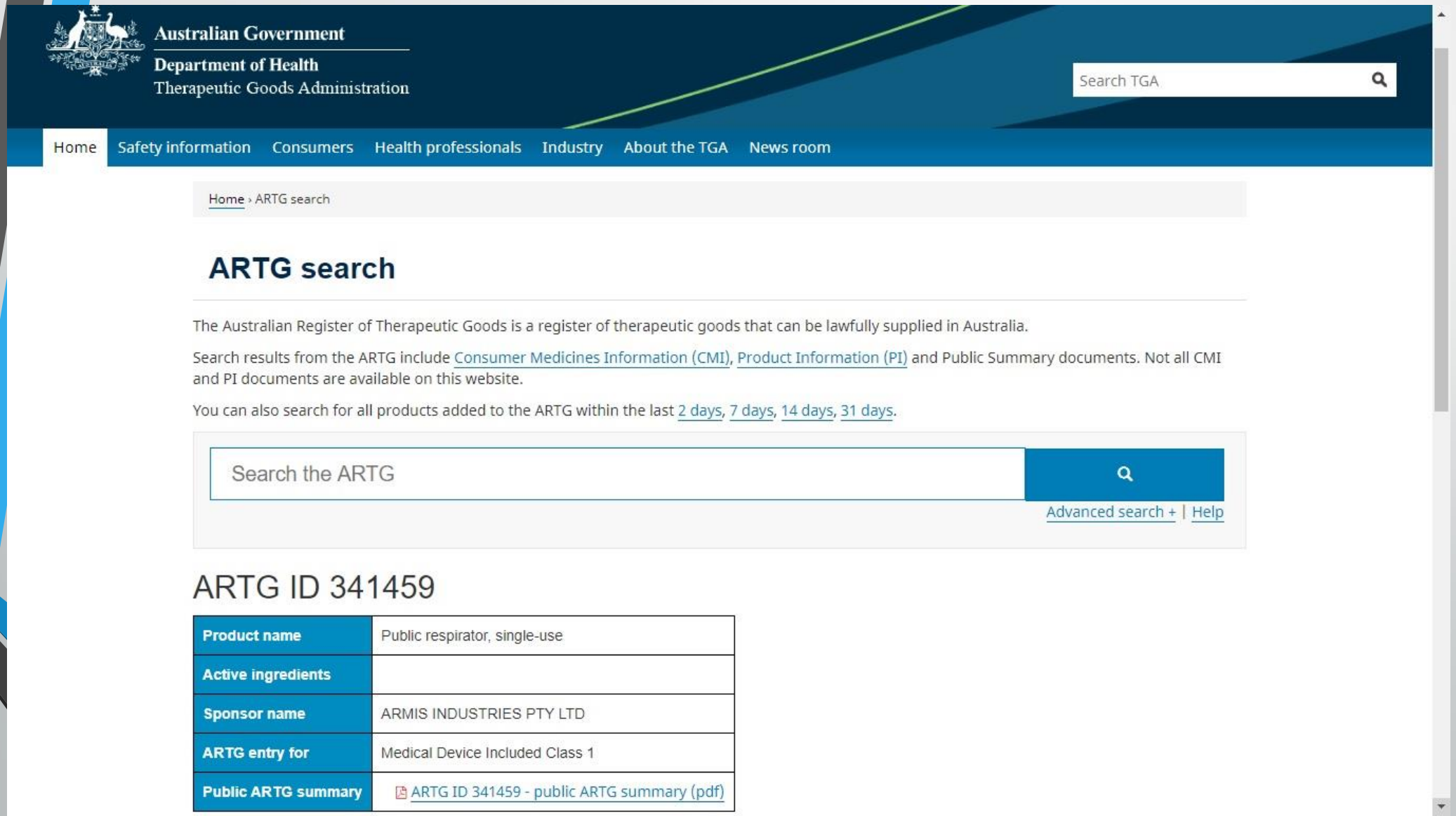
This is not an ARTG Certificate document.

The onus is on the reader to verify the current accuracy of the information on the document subsequent to the date shown.

Visit www.tga.gov.au for contact information

Public Summary

TGA System Record



Australian Government
Department of Health
Therapeutic Goods Administration

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Home › ARTG search

ARTG search

The Australian Register of Therapeutic Goods is a register of therapeutic goods that can be lawfully supplied in Australia.

Search results from the ARTG include Consumer Medicines Information (CMI), Product Information (PI) and Public Summary documents. Not all CMI and PI documents are available on this website.

You can also search for all products added to the ARTG within the last 2 days, 7 days, 14 days, 31 days.

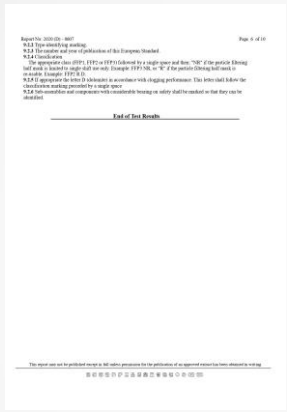
Search the ARTG

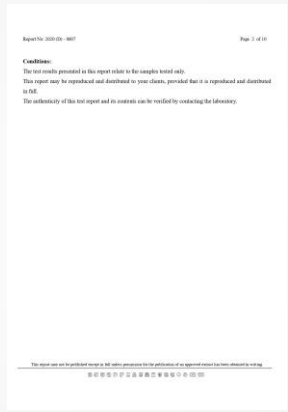
Advanced search + | Help

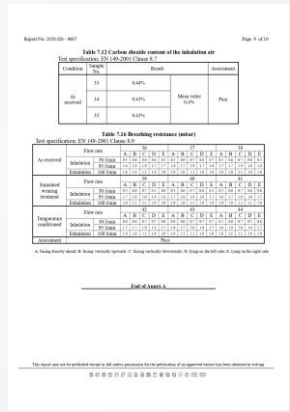
ARTG ID 341459

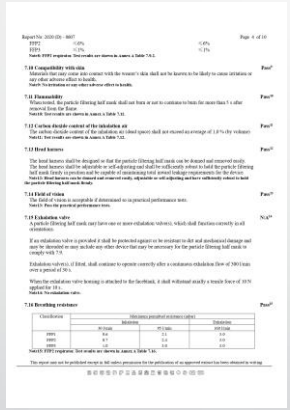
Product name	Public respirator, single-use
Active ingredients	
Sponsor name	ARMIS INDUSTRIES PTY LTD
ARTG entry for	Medical Device Included Class 1
Public ARTG summary	ARTG ID 341459 - public ARTG summary (pdf)

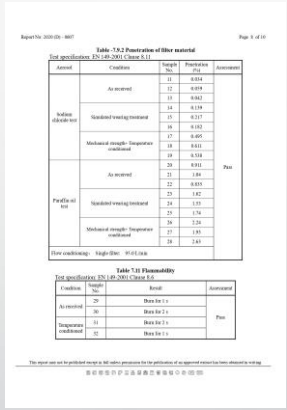
CE Test report EN 149-FFP2

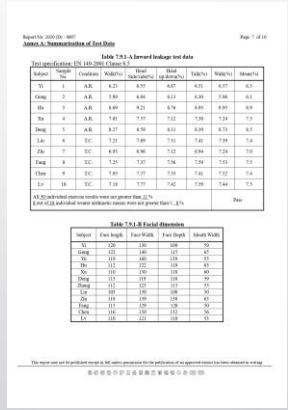


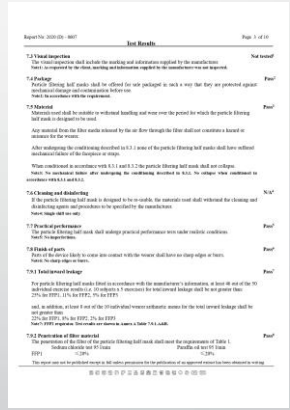


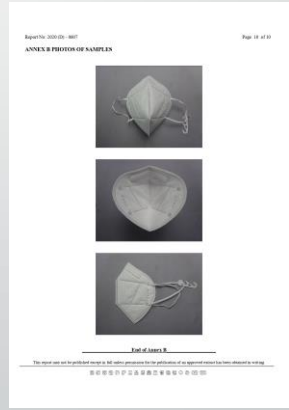


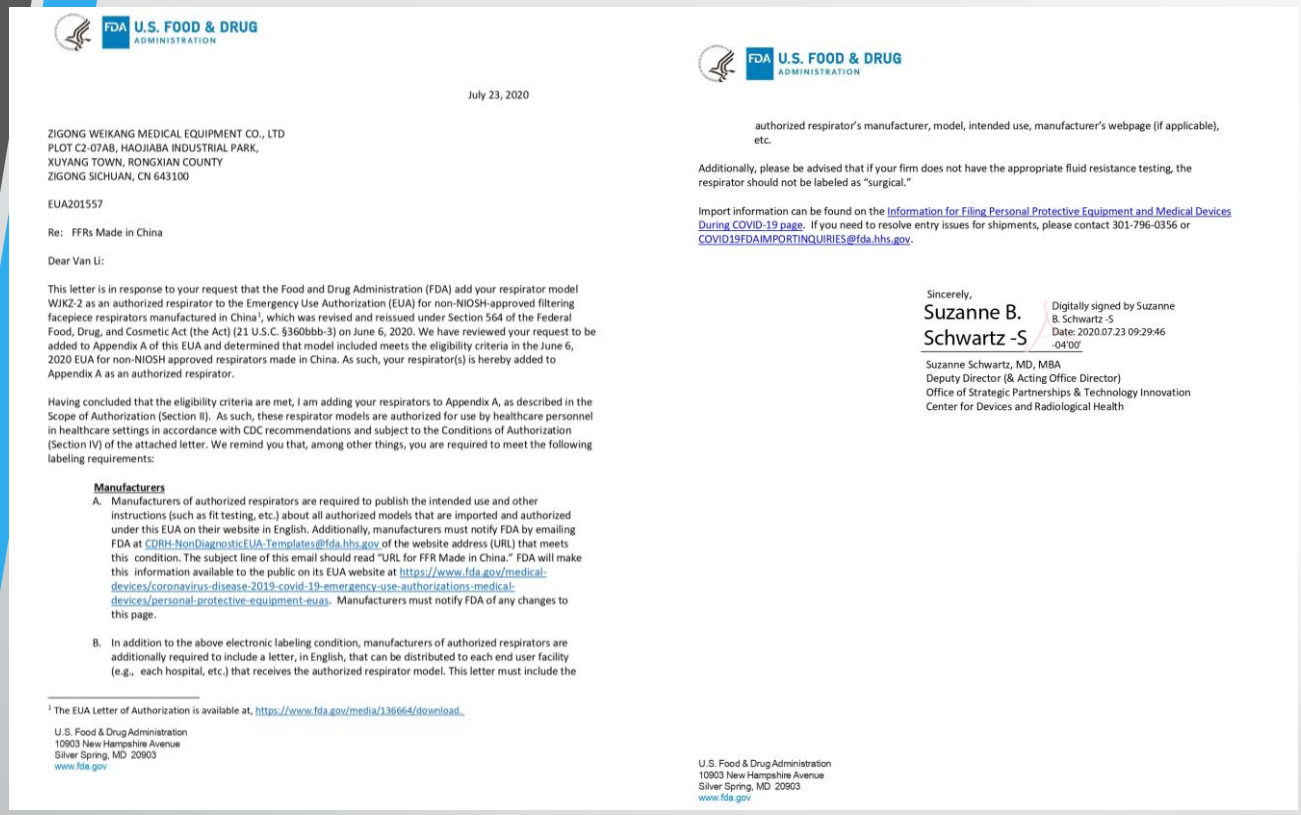












U.S. FOOD & DRUG ADMINISTRATION

July 23, 2020

ZIGONG WEIKANG MEDICAL EQUIPMENT CO., LTD
PLOT C2-07AB, HAOJIABA INDUSTRIAL PARK,
XUYANG TOWN, RONGXIAN COUNTY
ZIGONG SICHUAN, CN 643100

EUA201557

Re: FFRs Made in China

Dear Van Li:

This letter is in response to your request that the Food and Drug Administration (FDA) add your respirator model WJKZ-2 as an authorized respirator to the Emergency Use Authorization (EUA) for non-NIOSH-approved filtering facepiece respirators manufactured in China[1], which was revised and reissued under Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3) on June 6, 2020. We have reviewed your request to be added to Appendix A of this EUA and determined that model included meets the eligibility criteria in the June 6, 2020 EUA for non-NIOSH approved respirators made in China. As such, your respirator(s) is hereby added to Appendix A as an authorized respirator.

Having concluded that the eligibility criteria are met, I am adding your respirators to Appendix A, as described in the Scope of Authorization (Section II). As such, these respirator models are authorized for use by healthcare personnel in healthcare settings in accordance with CDC recommendations and subject to the Conditions of Authorization (Section IV) of the attached letter. We remind you that, among other things, you are required to meet the following labeling requirements:

Manufacturers

A. Manufacturers of authorized respirators are required to publish the intended use and other instructions (such as fit testing, etc.) about all authorized models that are imported and authorized under this EUA on their website in English. Additionally, manufacturers must notify FDA by emailing FDA at CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov of the website address (URL) that meets this condition. The subject line of this email should read "URL for FFR Made in China." FDA will make this information available to the public on its EUA website at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas. Manufacturers must notify FDA of any changes to this page.

B. In addition to the above electronic labeling condition, manufacturers of authorized respirators are additionally required to include a letter, in English, that can be distributed to each end user facility (e.g., each hospital, etc.) that receives the authorized respirator model. This letter must include the

[1] The EUA Letter of Authorization is available at, https://www.fda.gov/media/136664/download.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov

U.S. FOOD & DRUG ADMINISTRATION

authorized respirator's manufacturer, model, intended use, manufacturer's webpage (if applicable), etc.

Additionally, please be advised that if your firm does not have the appropriate fluid resistance testing, the respirator should not be labeled as "surgical."

Import information can be found on the Information for Filing Personal Protective Equipment and Medical Devices During COVID-19 page. If you need to resolve entry issues for shipments, please contact 301-796-0356 or COVID19FDAIMPORTINQUIRIES@fda.hhs.gov.

Sincerely,
Suzanne B. Schwartz -S
Digitally signed by Suzanne B. Schwartz -S
Date: 2020.07.23 09:29:46 -04'00'

Suzanne Schwartz, MD, MBA
Deputy Director (& Acting Office Director)
Office of Strategic Partnerships & Technology Innovation
Center for Devices and Radiological Health

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov

FDA Approved for EUA

Emergency Use Authorization in the US approved

Samples

Filtering Facepiece Respirators

KN95/ FFP2

WJKZ-2
FFP2 NR
CE 2834
EN 149:2001+A1:2009

FITTING INSTRUCTION

1. Hold the particle half mask in position over the nose and mouth.
2. Pull the headharness behind to ears, attach the headharness to the retaining clip, improve comfort and prevent leakage.
3. Ensure the nose clip is securely moulded around the nose, resting the ends against the cheek to obtain a good seal.
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, repositon the headharness for better fit.
5. Repeat adjustments until the mask is sealed properly.
6. If a proper seal cannot be achieved do not enter the contaminated area or it may cause illness.

Non-medical

Particle filtering half mask
Model : WJKZ-2
Classification : FFP2 NR
EN 149:2001+A1:2009
Regulation (EU) 2016/425
CE 2834

MADE IN CHINA

50 Respirators

PRODUCTION DATE :

Storage

1.Store the mask in a sealed container away from contaminated areas when not use.
2.Store the mask in the original packing during transport.

Period of validity: 3 years.

Notified body : CCQS Certification Services Limited
Address : Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin15, D15 AKK1, Ireland (NB 2834)
Manufacturer : ZI GONG WEIKANG MEDICAL EQUIPMENT CO., LTD
Address : C2-07sb, Hanjiahu Industrial Park, Xuyang Town, Rong County, Sichuan Province.

6 973079 510012

Model : WJKZ-2
FFP2 NR
CE 2834

USER INSTRUCTIONS

Failure to follow the instructions and warning on the use of this mask during all times of exposure can reduce the effectiveness of the mask and could result in illness or disability.
A copy of the Declaration of Conformity for this product can be found on the product page: www.mask-china.net
As with any respiratory device, the wearer must be adequately trained prior to use. Before use, the wearer should always check the mask is in good condition: no dirt, no damage to headharness attachment etc.

Limitation

Do not use the respirator or enter or stay in a contaminated area under the following circumstances:
a.Atmosphere contains less than 19. 5% oxygen.
b.If you smell or taste contaminant.
c.For protection against gases or vapors.
d.Contaminants or their concentrations are unknown or immediately dangerous to life or health.
e.For sandblasting, paint spray operations and asbestos treatment.
f.In explosive atmospheres.

Warning

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 manufacture.
3.This mask helps protect against certain particulate contaminants but does not completely eliminate exposure to the risk of contracting disease or infection.
4.It is unlikely that the requirements for leakage will be achieved if facial hair passes under the face seal.
5.Change the mask immediately if breathing becomes difficult or the mask becomes damaged or distorted.
6.Change the mask if a proper face seal cannot be achieved.

TGA Approved Packing and Label

Australian Register of Therapeutic Goods (ARTG) 341459 has been granted on the label

Packaging Details