

Covid-19 PPE

KN95 Face Masks

Covid-19

We are in unprecedented times. Covid-19 can spread even if individuals don't show symptoms which in turn will increase the number of cases exponentially. PPE, especially face masks, are in high demand as a result.

United States

Confirmed	Recovered	Deaths
956K	102K	53,928

Worldwide

Confirmed	Recovered	Deaths
2.89M	816K	202K

**as of 4/16/20*



PPE: Face Masks

- When someone that has Covid-19 coughs, sneezes, or talks, they send tiny droplets with the virus into the air
- Face masks cover your mouth and nose, blocking the release of virus-filled droplets into the air
- The CDC has already recommended wearing facemasks
- **All masks are NOT created with the same purpose and do NOT protect you equally**

Mask Differences: N95 vs. KN95

- KN95 has the closest comparable specs to the N95
 - filtering out 95% or more of the smallest particles in the air
- N95 are much needed by frontline health professionals so the best alternative for non medical use is the KN95
- As stay-at-home orders loosen, mask demand will spike for the general public and businesses
- *US forecast demand and spend on face mask in the billions*

Based on this comparison, it is reasonable to consider China KN95, AS/NZ P2, Korea 1st Class, and Japan DS FFRs as "equivalent" to US NIOSH N95 and European FFP2 respirators, for filtering non-oil-based particles such as those resulting from wildfires, PM 2.5 air pollution, volcanic eruptions, or bioaerosols (e.g. viruses). However, prior to selecting a respirator, users should consult their local respiratory protection regulations and requirements or check with their local public health authorities for selection guidance.

Certification/ Class (Standard)	N95 (NIOSH-42C FR84)	FFP2 (EN 149-2001)	KN95 (GB2626-20 06)	P2 (AS/NZ 1716:2012)	Korea 1 st Class (KMOEL - 2017-64)	DS (Japan JMHLW- Notification 214, 2018)
Filter performance – (must be ≥ X% efficient)	≥ 95%	≥ 94%	≥ 95%	≥ 94%	≥ 94%	≥ 95%
Test agent	NaCl	NaCl and paraffin oil	NaCl	NaCl	NaCl and paraffin oil	NaCl
Flow rate	85 L/min	95 L/min	85 L/min	95 L/min	95 L/min	85 L/min
Total inward leakage (TIL)* – tested on human subjects each performing exercises	N/A	≤ 8% leakage (arithmetic mean)	≤ 8% leakage (arithmetic mean)	≤ 8% leakage (individual and arithmetic mean)	≤ 8% leakage (arithmetic mean)	Inward Leakage measured and included in User Instructions
Inhalation resistance – max pressure drop	≤ 343 Pa	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min) ≤ 500 Pa (clogging)	≤ 350 Pa	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min)	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min)	≤ 70 Pa (w/valve) ≤ 50 Pa (no valve)
Flow rate	85 L/min	Varied – see above	85 L/min	Varied – see above	Varied – see above	40 L/min
Exhalation resistance - max pressure drop	≤ 245 Pa	≤ 300 Pa	≤ 250 Pa	≤ 120 Pa	≤ 300 Pa	≤ 70 Pa (w/valve) ≤ 50 Pa (no valve)
Flow rate	85 L/min	160 L/min	85 L/min	85 L/min	160 L/min	40 L/min
Exhalation valve leakage requirement	Leak rate ≤ 30 mL/min	N/A	Depressurizati on to 0 Pa ≥ 20 sec	Leak rate ≤ 30 mL/min	visual inspection after 300 L /min for 30 sec	Depressurizatio n to 0 Pa ≥ 15 sec
Force applied	-245 Pa	N/A	-1180 Pa	-250 Pa	N/A	-1,470 Pa
CO ₂ clearance requirement	N/A	≤ 1%	≤ 1%	≤ 1%	≤ 1%	≤ 1%

*Japan JMHLW-Notification 214 requires an Inward Leakage test rather than a TIL test.

ZhiZhen KN95 Mask

*What's the difference between KN95
and all the other masks on the market ?*



Quality Mask

CE and FDA registration to filter 95% or more with supporting documentation available. There are a lot of fake and substandard products on the market.



Retail Packaging

Single packed masks in a professional sealed retail envelope not bulk or OEM packed.

FDA Registration

- Guangdong ZhiZhen Biological KN95 is on the FDA Appendix A: Authorized Respirators which was updated on April 24, 2020
- <https://www.fda.gov/media/136663/download>
- 1 of 90 companies the FDA have listed for Non-NIOSH Approved Respirators Manufactured in China



Fiscal Year 2020
CERTIFICATION OF FDA REGISTRATION

This certifies that:

Guangdong ZhiZhen Biological Medicine Co., Ltd.
No.5 South Street, Datian First Team, Minzhu Village, Tanbu Town,
Huadu District, Guangzhou 510820, CHINA

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through

Shenzhen CCT Testing Technology Co., Ltd.

Owner/Operator Number: 10062984

Device Listing#: See Next pager

CCT will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. CCT 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-holder's device or establishment by the U.S. Food and Drug Administration. CCT assumes no liability to any person or entity in connection with the foregoing.

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Expiration Date: 12/31/2020

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Fiscal Year 2020
CERTIFICATION OF FDA REGISTRATION

Listing#:

Reg No	Code	Device Name	Proprietary Name
30	MDM	INSTRUMENT, MANUAL, SURGICAL, GENERAL USE	Face Mask
29	OEA	Non-surgical isolation gown	Protective clothing
28	HQY	Sunglasses (non-prescription including photosensitive)	Goggles
27	KHA	MASK, SCAVENGING	Mask



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Wholesale Price

- You are welcome to use your own freight forwarder
- Transit, duties, and taxes not included
- Due to demand and quantity of order, lead time from payment can take 13-20 days
 - Transit exceptions and customs delays are not accounted
- Prices subject to change until finalized by payment, prepayment is required
- Competitive bulk / wholesale pricing available for quantities greater than 10,000 masks

Contact

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