

USES AND WARNINGS

HEALTH CARE PARTICULATE RESPIRATOR AND SURGICAL APPAREL, KN95

Approvals and Standards:

- KN95 rated particulate respirator
- Meets GB2626-2006 requirements for a minimum 95% filtration efficiency for solid and liquid aerosols that do not contain oil
- FDA Class 1 Approved for Surgical Apparel

Use For:

- Intended to be worn by healthcare personnel during general and plastic surgical procedures
- Always follow User Instructions and use in manners as indicated

Do Not Use For:

- DO NOT use in industrial settings
- DO NOT use for gases or vapors (i.e. anesthetic gases such as isoflurane or vapors from sterilants such as glutaraldehyde.)
- DO NOT use in any manner not indicated in the User Instructions

Time Use Limitation:

This particulate respirator may be used until damaged, breathing becomes difficult or contaminated with blood or body fluids. Discard after every use when used for surgical procedures. Follow national, state, local, and facility infection control guidance and policies.

Shelf Life and Storage:

- 5 years from the date of manufacture
- Store particulate respirators in the original packaging, away from contaminated areas, dust, sunlight, extreme temperatures, excessive moisture, and damaging chemicals
- Store in temperatures between -22°F (-30°C) and +104°F (+40°C) and not exceeding 80% RH

WARNING!

This particulate respirator helps protect against certain particulate contaminants but does not eliminate exposure to or the risk of contracting any disease or infection. Before use, the wearer must read and understand the User Instructions provided as a part of the product packaging. Follow all local regulations. Misuse may result in sickness or death. For correct use, consult supervisor and the User Instructions.

COMPARISON OF FACEPIECE RESPIRATOR CLASSES

Based on this 3M 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	Depressurization to 0 Pa ≥ 20 sec	Leak rate ≤ 30 mL/min	visual inspection after 300 L / min for 30 sec	Depressurization to 0 Pa ≥ 15 sec
Force applied	-245 Pa	N/A	-1180Pa	-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.