









# Isolator™ Plus N95 Surgical Respirator Instructions for Use

## Symbols used:

	See manufacturer's instructions for use
	Attention: Follow instructions for use
	Maximum storage time: Month/year
	Storage temperature range
	Relative humidity
	Lot number, batch number
	Conformity according Medical Device Directive MDD 93/42/EEC
	Do not reuse

## Checks prior to use:

Check for any visible damage.

Check expiration date.

Damaged or soiled particle filtering half masks or particle filtering half masks where the expiration date has elapsed must not be used.

## Directions for use:

- Grasp nosepiece at top of mask with one hand. Slide finger of other hand behind chinpiece.
- Open mask by pulling down and out on chinpiece until mask is fully open. It is IMPORTANT that mask is fully open.
- Place chin in pocket created. Stretch bands over back of head, positioning bottom band behind neck below ears and top band near crown of head.
- Conform nosepiece to nose and face contours making sure support arch is fully extended away from nose and mouth.
- Holding mask at nosepiece, place one finger inside the mask on the malleable aluminum chinpiece, pull down gently so that mask is snug against face.
- Pinch any excess material together under chin and fold over or twist.
- Face Fit Check: Place both hands along edges of the respirator and exhale. If air escapes around nose, adjust nosepiece. If air leaks at respirator edges, unfold or untwist the chinpiece, repeat steps 5 & 6.

## Warning:

- This product does not eliminate the risk of contracting any disease or infection. Change immediately if the respirator comes in contact with blood or fluids, including body fluids. OSHA has not set a permissible exposure level for airborne biohazards.
- Follow all instructions and warnings on the use of this respirator. Failure to do so will reduce respirator effectiveness, wearer protection and may result in sickness or death. Wear during all times of exposure. For additional information refer to your supervisor and/or see dispenser box.
- Before use, the wearer must be trained by the employer in proper respirator use in accordance with applicable safety and health standards for the contaminant and exposure level in the assigned work area.

## Description:

The Isolator™ Plus N95 Surgical Respirator provides high filtration of submicron particles for protection against certain airborne particulates in accordance with the CDC guidelines for TB exposure control. These products are NIOSH approved as N95 particulate filter respirators (95% particulate filter efficiency level) and therefore meet OSHA requirements when used with an acceptable respirator program.

- Malleable aluminum band over the nose and under the chin provides a comfortable, custom fit which completely seals the periphery.
- Eliminates "blow-by" while providing maximum breathability.
- Eliminates fogging of glasses, surgical loupes or protective eyewear.
- Sustained filtration.
- More functional breathing area.
- Cooler comfort due to mask relief from face.
- No restriction of "down vision."

Test results for filtration available on request.

This respirator is only approved for the following configurations:

TC-84A-0457	Protection <sup>1</sup> N95	RESPIRATOR No. GPRN95	Cautions and limitations <sup>2</sup> ABCJMNOPS
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## 1. Protection

N95 Particulate Filter (95% filter efficiency level) effective against particulate aerosols free of oil: time use restrictions may apply.

## 2. Cautions and limitations

- A Not for use in atmospheres containing less than 19.5% oxygen.
- B Not for use in atmospheres immediately dangerous to life or health.
- C Do not exceed maximum use concentrations established by regulatory standards.
- J Failure to properly use and maintain this product could result in injury or death.
- M All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.
- N Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configurations as specified by the manufacturer.
- O Refer to user instructions and/or maintenance manuals for information on use and maintenance of these respirators.
- P NIOSH does not evaluate respirators as surgical masks.
- S Special or critical User's instructions and/or specific limitations apply. Refer to User's instructions before donning.

## European Standard EN 149:2001

Isolator Plus N95 Surgical Respirator also meets the requirements of European Standard EN 149:2001 FFP2 NR:

Device Class:	Multiple of limit values:	Remarks, restrictions:
Particle filtering half mask FFP2	10	Not effective against particles of radioactive materials and enzymes.

\* Limit values for example are those limits specified in TRGS 900 relating to air at the workplace - MAC and TRK values (MAC = maximum allowable concentration at place of work; TRK = technical guideline concentration)

- Only for use in healthcare settings.
- Not to be used in areas with open flames.
- National regulations must be observed, e.g. BGR 190 (formerly ZH1/701) – Rules for the application and use of respirators; BGI 504-26 (formerly ZH11600.26) – Selection criteria for use in occupational medicine according to the rules of trade association, G26 "respiratory protective devices".
- The user must be familiar with the use and handling of the device.
- Unventilated containers, pits, sewers and confined areas must not be entered with particle filtering half masks.
- Type and concentration of the hazardous substances must be known.
- Particle filtering half masks do not offer protection against gases and vapors. The mask must be replaced when high airway resistance is noticeable.
- The mask should only be used for maximum one working shift.
- Respiratory protective devices must be selected according to the type and concentration of the hazardous substance.
- Respiratory protective devices are not suitable for persons with beards, sideburns or deep scars in the area of the sealing lines of the face pieces.
- In the event of an oxygen deficiency, harmful concentrations of hazardous substances or unknown conditions, self-contained closed-circuit compressed oxygen breathing apparatus must be used independent of the environment.

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