



ENMED® ENM - 313 3 PLY UTRASONIC SURGICAL MASK (TYPE II-R)

The ENMED ENM - 313 3 PLY UTRASONIC SURGICAL MASK (TYPE II-R) is intended to be worn by medical personel, patients and people to protect from transfer of microorganisms, body fluid and particulate material transfer. Type II-R Face masks include a splash resistant layer to protect against blood and other bodily fluids. Type IIR face masks are tested in the direction of exhalation (inside to outside) and take into account the efficiency of bacterial filtration.

KEY FEATURES

- The products are for single use only.
- Latex Free
- · Hypoallergenic
- Fiberglass free
- Fluid Resistant
- Three Ply construction
- 3 pleats of folds to allow the user to expand the mask so it covers the area from the nose to the chin.
- · Mask allows itself to be secured with an ear loop when placed behind the ears.
- · Reduces exposure to blood and body fluids.
- · Minimizes Doctor and patient contamination to exhaled microorganisms.

COUNTER INDICATION

None in particular.

PROPERTIES

Bacterial Filtration Efficiency (BFE): >98% Breathing resistance: <40 Pa/cm2 Splash Resistance of ≥16 kPa

EN 14683 classification: Type IIR facemasks

INTENDED USE

3 ply mask is intended to be worn by

Medical personel, patients and people to protect from transfer of microorganisms, body fluid and particulate material transfer.

DONNING INSTRUCTIONS

- The mask should be worn so that it covers the mouth and nose completely and there is no gap between the face and the mask.
- Touching the mask while wearing should be avoided, and hands should be washed with soapy water after touching a used mask. In the absence of water, antibacterial gel should be used.
- When the mask gets wet or moist, it should be replaced with a new dry mask.
 Moisture can cause diaper rash and irritation in that area.
- · Torn, punctured or damaged masks should not be used.
- The mask is personal and Damp, wet products should never be used.

STORAGE CONDITIONS

- Unopened package can be used for 5 years from the date of manufacture.
- · Store in a dry and cool place, away from intense sources of heat.

WARNINGS AND LIMITATIONS

- Do not use the product other than its intended use.
- · Never use wet and moist products.
- The products are for single use only.
- Do not use it again when you remove it.
- It is personal. Never use someone else's mask.
- Our products have been tested. However, We recommend it not to be used on sensitive skin and if allergic to any materials used.

TECHNICAL DATA

| MATERIAL | Multilayer SMS Fabric |
|------------|--|
| COLOR | Blue, Green, White |
| HEADBAND | Latex free elastic ear loops, white, 17 cm |
| SIZES | Universal (17cm x 9cm) |
| PACKAGING | Optional packaging of 1/4/10/50/100 |
| Nose Clips | Optional Aluminum Nose Clips |
| C00 | TURKEY |

PRODUCT OVERVIEW

A surgical mask is intended to prevent the release of potential contaminants from the user into their immediate environment which can also protect the wearer from large droplets, sprays and splashes of bodily fluids. It is easily identifiable by the presence of two ear loops to secure the mask to the face for quick donning.

Procedure masks are used on hospital floors, isolation units, and labor and delivery units, among other areas of the hospital for generally to prevent clinicians, patients and visitors from spreading germs by talking, coughing, or sneezing.

These masks may also be used in the emergency department and the intensive care unit. However, beware that some specifications are non-sterile and designed for clean environments which not suitable for use in the operating room.

Our disposable surgical face masks contain 3 layers:

a mix of non-woven fabric and a middle

melt-blown material that acts as a filter and have a >99% particle filtration efficiency (PFE). They provide physical barrier that protects both wearers and others from the transfer of respiratory

secretions, fluids or other debris and avoid the contamination of bacteria or viruses present in mucus and saliva.

WASHING INSTRUCTIONS

Our products do not have a washing feature.

REGULATORY INFORMATION

Product CE marked as per 93/42/EEC Directive on Medical Devices. Class of the device: I.

Product compliant with EN14683





HOW TO PROPERLY WEAR A FACE MASK



ENSURE THE PROPER SIDE OF THE MASK FACES OUTWARDS



SECURE THE STRINGS BEHIND YOUR HEAD OR OVER YOUR EARS



PRESS THE NOSE CLIP TO FIT THE SHAPE OF THE NOSE



COVER MOUTH AND NOSE FULLY MAKING SURE THERE ARE NO GAPS



WEAR MASK



DO NOT TOUCH THE MASK WHILE USING IT, IF YOU DO WASH YOUR HANDS



REMOVE THE MASK FROM BEHIND BY HOLDING THE STRINGS WITH CLEAN HANDS



ENM - 313 3 PLY UTRASONIC SURGICAL MASK (TYPE II-R)

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| Product | 3 PLY UTRASONIC SURGICAL MASK (TYPE II-R) | |
| Material | Outer layer: 20 Gsm Spunbound (175mm) | |
| | Filter layer: 25 Gsm Meltblown (BFE >%99) (175mm) | |
| | Inner layer: 30 Gsm Spunbound (200mm) | |
| Size | 17cm x 9 cm | |
| Color | Blue, Green, White | |
| Nose Clips | Optional Aluminum Nose Clips | |
| Standard | 1- BFE >%99 | |
| | 2- PFE >%95 | |
| | Polypropylene inner and outer facing assures comfortable on the inside and protection on the outside; | |
| Certificate | CE, ISO, FDA | |