

TECHNICAL FILE FOR DEVICE:**SURGICAL MEDICAL 3-LAYER DISPOSABLE FACE MASK**
TYPE I and II**General Description**

Medical 3-layer masks, latex free, fiber glass free, hypo-allergic, with ear loops and nose piece. Three (3) ply, splash resistant,

One size masks

Box of 50pcs

Synonym: Procedure /face masks / medical mask

Intended Use

Medical mask is intended to be worn by medical personnel during surgical or other medical procedures to protect both the patient and the operating personnel from transfer of microorganisms, body fluid and particulate material transfer. It can be also worn for protection against viruses and bacteria propagation in droplets of human body - for regular citizens.

Reduces exposure to blood and body fluids in droplets. Minimizes patient contamination to exhaled microorganisms. This product is intended for use in infection control practices.

Technical Specifications**TYPE I****Mask construction includes:**

1. Main part made of nonwoven and melt blown fabrics.

1.1 Spunbound nonwoven polypropylene 20g-35g/m² for inner and outer layers of mask.

1.2 Melt blown polypropylene BFE95 20-35g/m² for middle, filtration layer of mask.

One of the conditions must be fulfilled:

>95% Bacterial Filtration Efficiency (BFE) at 5 micron capacity;

or

>90% Bacteria Filtration Efficiency (BFE) at 3 micron capacity.

Condition varies according to exact Laboratory test method.

Internal layer do not fluff.

No materials used contains fiberglass.

TYPE II

Mask construction includes:

1. Main part made of nonwoven and melt blown fabrics.

1.1 Spunbound nonwoven polypropylene 20g-35g/m² for inner and outer layers of mask.

1.2 Melt blown polypropylene BFE99 20-35g/m² for middle, filtration layer of mask.

One of the conditions must be fulfilled:

>99% Bacterial Filtration Efficiency (BFE) at 5 micron capacity;

or

>95% Bacteria Filtration Efficiency (BFE) at 3 micron capacity.

Condition varies according to exact Laboratory test method.

Internal layer do not fluff.

No materials used contains fiberglass.

1.3 Main part size: 175 x 95mm. Three Ply construction sealed with ultrasonic pressing machine. 3 pleats of folds to allow the user to expand the mask so it covers the area from the nose to the chin.

1.4 Color: Blue, White, Green, Purple

2. Nose bridge for possibility to shape by hand upper edge, to follow nose shape and make mask more airtight. Made of plastic and soft wire.

3. Ear loops welded to main part with ultrasonic welder, made of latex free rubber with plaited shield.

Usage: For Single use only.

CE marked.

Primary packaging: Unit of use (1) box of 50 masks

Secondary packaging: 24 cases of 50 masks /box (1200 pieces/case)

Labelling on the primary packaging:



Manufacturer:



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Complies with PN-EN 14683+AC:2019-09

LOT



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EN Medical, disposable face mask

3-layers, with earloops, type II, single use

Instruction:

Grab the rubber bands with your hands and attach to your ears to cover your mouth and nose.

Shape the upper edge of the mask to allow it to follow nose shape.

After use, remove by touching only earloops, throw away and wash your hands thoroughly.

PL Maska medyczna

3-warstwowa, z gumkami, typ II, jednorazowego użytku

Instrukcja:

Chwyć dłońmi za gumki i załóż na uszy, upewnij się, że maska zasłania usta i nos.

Uformuj górną krawędź maski, aby ściśle przylegała do skóry.

Po użyciu zdejmij, dotykając wyłącznie gumek zauszników, wyrzuć i umyj starannie ręce.



PL Maska medyczna, jednorazowego użytku, z gumkami

EN Medical mask, disposable, with earloops

DE Einweg-Schutzmaske, mit Gummi

FR Masque médical, jetable, avec élastiques

RU медицинская маска, одноразовая, на резинках

ES Mascarilla médica, desechable, con gomas

IT Mascherina medica, monouso, con elastici

AR قناع طبي قابل التخلص، مع حلقات مطاطية

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