



EU MDR FACE MASKS

Surgical Face Masks
Protective Masks



Innovation
Health & Medical



Our Quality and Strengths

Investments in technology are the foundation of high quality. In our research and development (R&D) labs, we focus on technology, customer happiness, and meeting the needed demands before we market or produce any of our products.

Our imprints are practically wherever we go, in addition to the many services we offer. By providing products with superior performance at cheaper costs, we assist our customers in maintaining their budgets.

Along with the OPIA Medical brand and other strategic brands, we are proud to support our customers in our B2B and B2C operations. We are also proud to make our customers lives better.

For the industries we have served, our goal is to develop innovative goods on a global scale. We also work to understand our customers' demands by researching their global, regional, and demographic features.



Highest Standards of Protection and Breathability

Highest Standards of Protection and Breathability

OPIA Medical manufactures surgical masks and protective masks in accordance with strict quality and safety guidelines. The main reason for this is that its developers are doctors and surgeons. Our surgical masks and respirators are made to the highest levels of protection while providing outstanding comfort. Our masks are made to fulfil the demands of medical professionals, including nurses and surgeons.

European Standard En 14683 Medical Face Mask Requirements

The face mask selection from OPIA Medical complies with the European Standard EN14683 in terms of production, design, and performance. Before being placed on the market, face masks are examined for their biological safety by OPIA Medical and tested for bacterial filtration effectiveness, differential pressure, splash resistance, and microbiological cleanliness. A wide variety of latex-free procedural and surgical face masks that adhere to EN14683 Type II or Type IIR standards are available from OPIA Medical.

	Bacterial Filtration Efficiency(%)	Differential Pressure(Pa/cm)	Bounce Pressure Resistance (kPa)	Microbial Cleaning(kPa)
Type II	≥ 98	≤ 40	Not required	≤ 30
Type IIR	≥ 98	≤ 60	16	≤ 30



Special Protection Packaging



MODEL NO: OP-MASK-0020	TYPE IIR SURGICAL MASK			
	Bacterial Filtration Efficiency (%) ≥98	Differential Pressure (Pa/cm2) ≤ 60	EN 14683 TYPE IIR	Packaging 1 Box : 50 Pieces 1 Package : 48 Box 1 Package : 2400 Pieces
MODEL NO: OP-MASK-0010	TYPE II SURGICAL MASK			
	Bacterial Filtration Efficiency (%) ≥98	Differential Pressure (Pa/cm2) ≤ 40	EN 14683 TYPE II	Packaging 1 Box : 50 Pieces 1 Package : 48 Box 1 Package : 2400 Pieces
MODEL NO: OP-MASK-0060	KIDS FACE MASKESİ			
	Bacterial Filtration Efficiency (%) ≥98	Differential Pressure (Pa/cm2) ≤ 60	EN 14683 TYPE IIR	Packaging 1 Box : 50 Pieces 1 Package : 48 Box 1 Package : 2400 Pieces
MODEL NO: OP-MASK-0050	BELTED MASK			
	Bacterial Filtration Efficiency (%) ≥98	Differential Pressure (Pa/cm2) ≤ 60	EN 14683 TYPE IIR	Packaging 1 Box : 50 Pieces 1 Package : 48 Box 1 Package : 2400 Pieces
MODEL NO: OP-MASK-0030	ANTI-FOG & ANTI-EYE SURGICAL FACIAL MASK			
	Bacterial Filtration Efficiency (%) ≥98	Differential Pressure (Pa/cm2) ≤ 60	EN 14683 TYPE IIR	Packaging 1 Box : 50 Pieces 1 Package : 48 Box 1 Package : 2400 Pieces
MODEL NO: OP-MASK-0040	FACIAL MASK FOR SKIN COMFORT (CELLULOSE INNER COATING)			
	Bacterial Filtration Efficiency (%) ≥98	Differential Pressure (Pa/cm2) ≤ 60	EN 14683 TYPE IIR	Packaging 1 Box : 50 Pieces 1 Package : 48 Box 1 Package : 2400 Pieces

Surgical Face Mask

This type of face mask should be used during possible exposure to pathogens. It is effective against contamination by droplets (saliva and other secretions).

Protection against airborne pathogens is not possible. There are three classifications according to EN 1468 standards (Type I, Type II, and Type IIR). However, OPIA Medical carries only the following classifications:

Type II Surgical Mask

Type II masks are often designed for use by health professionals in operating rooms and other similar medical environments..

Type IIR Surgical Mask

When performing surgery or providing patient care where exposure to biological fluids is likely, type IIR face masks may be worn.

Face masks from OPIA Medical, Type IIR offer excellent liquid protection and are appropriate for lengthy treatments. There are various alternatives to raise the level of safety and comfort (protection, mist preventive tape, etc.).

There are additional Type IIR face masks with easy-to-use ear loops available.

TYPE II SURGICAL MASK MODEL NO : OP-MASK-0010

Our OPIA Medical Type II surgical face masks are intended for use in operating rooms and other care facilities with requirements similar to those found in healthcare institutions.

Technical Specifications :

- It is disposable.
- 3-layer superior filtration technology
- Inner layer of nonwoven spun bond fabric
- The middle layer is nonwoven and melt blown.
- Outer layer of nonwoven spun bond fabric
- Elastic PP 3/3 stretchable quality ear floss
- The front part is made of aluminium wire, which can be bent into any shape appropriate for the face.
- PP-coated nose wire
- Ultrasonic special design that is seamless
- Fully compatible with other PPE (glasses, visor, etc.)
- It does not contain allergic materials such as latex or fiberglass.
- 50 box packages with disposable bags
- Available in packs of 10.
- 50 Pieces / Box
- Box / Piece 2400
- It performs 99.99% bacterial filtration.
- It is produced to the EN 14683 standard.

TYPE IIR SURGICAL MASK

MODEL NO: OP-MASK-0020

OPIA Medical Type IIR surgical face masks should be used during surgical intervention or patient care procedures where exposure to biological fluids is likely. Type IIR surgical face masks offer a high level of protection against liquids and are suitable for long procedures.

Technical Specifications:

- 3-layer, easy to breathe
- In accordance with Type IIR specifications
- A quality melt blown filter is used.
- Produced from PP (non-woven synthetic material).
- It can be fixed to the nose part thanks to the wire clip.
- It is flexible and soft, and it is fully compatible with the face.
- It is round, elastic and ultrasonic stitched.
- Box packages of 50 pieces are available in disposable bags and as packages of 1.
- Box/Pieces 2400 • 50 Pieces/Box
- It performs 99.99% bacterial filtration.
- Production is made in accordance with the EN 14683 standard.



KIDS FACE MASK

MODEL NO: OP-MASK-0060

Technical Specifications:

- 3-ply filtered ear loop mask for children.
- Bacterial filtration with Melt blown
- Spun bond non-woven material
- Ultrasonic sewing
- Soft polypropylene (PP) coated
- Nose wire is adjustable
- Elastic
- Anti-allergic, air permeable
- Latex is fibreglass free.
- It is produced in various colours and patterns.
- Disposable
- 50 Pieces/Box
- Box/Piece 2400
- It is produced to the EN 14683 standard.



BELTED MASK MODEL NO: OP-MASK-0050

Technical Specifications:

- Spun bond nonwoven material
- EN 14683, Type IIR,
- BFE > 99.0% filtration property
- Ultrasonic stitches
- Soft polypropylene (PP) coated
- Nose wire is adjustable
- Anti-allergic, air permeable
- Fiberglass, latex-free
- Disposable
- 50 Pieces/Box
- Box/Piece 2400
- It is produced to the EN 14683 standard.
- It is produced in various colours.

ANTI-FOG AND ANTI-EYE SURGICAL FACIAL MASK MODEL NO: OP-MASK-0030

Surgical face mask that prevents eye and nose fog; Its purpose is to stop disease from spreading from a healthcare professional to a patient (e.g. swelling, mucous membranes, influenza infection, upper respiratory, lower respiratory infections). Additionally, it is used to lessen the possibility that splashes or sprays from substances like blood, body fluids, secretions, and excretions will end up in the user's mouth or nose.

Technical Specifications:

- Cellulose inner lining for skin comfort.
- Mask with an eye shield
- Melt blown layer
- EN 14683,
- Type IIR,
- High filtration efficiency
- BFE>99%
- A moulded nose bridge with a soft foam nose pad provides the wearer an easy, comfortable and reliable fit.
- Optical quality eye shield that prevents fogging.
- Panoramic visor: ideal for situations where there is a high risk of exposure to blood or other body fluids.
- Anti-glare can be used with the visor for better comfort.
- It provides maximum visibility and face protection.
- Ultrasonic sewing-polypropylene (PP) coated soft adjustable nose wire
- Anti-allergic, air permeable
- Latex is fibreglass free.
- Disposable
- 50 Pieces/Box, 1000 Pieces/ Carton
- It is produced to the EN 14683 standard.
- It is produced in various colours.



FACIAL MASK FOR SKIN COM-
FORT (CELLULOSE INNER
COATING)
MODEL NO :OP-MASK-0040

Technical Specifications :

- Ear loop
- Three-ply cellulose mask (Meltblown) with bacterial filtration
- EN 14683, Type IIR, high filtration efficiency
- Ultrasonic sewing-soft polypropylene (PP) coated
- Nose wire is adjustable
- Round elastic, spandex (Latex-free)
- Anti-allergic, air permeable, latex and fibreglass free.
- Disposable
- 50 Pieces / Box, 2400 Pieces / Carton
- Can be produced in various colors.



OPIA MEDICAL FFP MASKS

Some hazardous particles may harm the respiratory system, while others may cause cancer or be radioactive. Long-term exposure can result in serious sickness. Face masks with OPIA Medical filter technology offer three grades of protection against tiny particles, smoke, and liquid oil aerosols while in use. Its defence mechanisms abide by EU standard EN 149. These face masks are classified as FFP1, FFP2, and FFP3 protection grades and are also known as particulate filter half masks or fine particle masks.

WHERE ARE OPIA MEDICAL RESPIRATORY MASKS USED?

Filter face masks offer defence against inhalable liquid, smoke, dust, and aerosols. Three FFP classes make up the classification scheme. Filter face mask is referred to as FFP. The respirator has a mask and several filter materials that cover the mouth and nose. They must be utilised in settings where the exposure limit values are exceeded (OEL).

WHAT DO OPIA MEDICAL RESPIRATORY MASKS PROTECT AGAINST?

Respirators in classes FFP1, FFP2, and FFP3 provide respiratory protection against a range of pollutant densities based on total leakage and filtering of particles up to 0.6µm. Based on filter penetration and leaks in the mouth and nose, total leakage is determined. In order to prevent this, the masks of our OPIA Medical respirators have been modified to fit the human structure. Thanks to the innovative filter technology, respiratory resistance can be kept to a minimum and breathing is so much more comfortable due to the particles trapped in the filter after multiple studies.

Class /Grade	Maximum Total Allowed Infiltration	Max. Permissible Penetration of Filter Material	Min. Filtering Effectiveness	Nominal Protection Factor * (NPF)	Assigned Protection Factor** (APF)
FFP1	22%	20%	80%	4,5	4
FFP2	8%	6%	94%	12,5	10
FFP3	2%	1%	99%	50	20

FFP2 MASKE MODEL NO : OP-MASK-0110

OPIA Medical, FFP2 protection class respirators, which are in the PPE category, have been created for working environments where dangerous and mutagenic particles can be found in the air. Respirators in this class must retain at least 94% of particles down to 0.6µm and can be used in environments where the OEL violation occurs at a maximum concentration of ten times. The same applies to the TRK value (technical reference density). FFP2 protection class respirators are mostly used in hospital, iron and mining industries. Workers in these industries are frequently exposed to aerosols, soot and fumes. This can cause respiratory system diseases such as lung cancer in the long run. In addition, they carry a very large risk of secondary disease and pulmonary tuberculosis. Our carbon-layered OPIA filter system not only provides the necessary respiratory protection, but also protects users from unpleasant odours.

Technical Specifications :

- Protective mask hazard type: FFP2
- Mining industries such as iron and operating rooms
- Respiratory protection
- Equipment
- Type of closure: flexible holder
- Fabric has five layers.
- 95% filtration efficiency
- The box contains ten pieces.
- Dimensions of the box: 126 mm * 44 mm * 180 mm
- Box weight: 100 gr.
- It is produced in various colours.



FFP3 MASK MODEL NO : OP-MASK-0111

Opia Medical offers the highest level of protection in the PPE category for FFP3 protection class respirators. These masks filter out 99% of all particles down to 0.6 m, and total leakage is limited to no more than 2%. Additionally, this mask screens out radioactive and hazardous particles. Masks of the FFP3 protection class are worn in settings where the industry-specific OEL values are thirty times higher. They are primarily employed in the chemical sector.

Technical Specifications :

- It is manufactured in accordance with EN 149:2001.
- Protection from all kinds of harmful, toxic dust, smoke, and aerosol
- Oncogenes and radioactive substances or pathogens such as viruses, bacteria, and fungal spores are filtered out by this class of protective respiratory mask.
- The total amount of infiltration can be no more than 2%.
- Property Violation of Thirty Times Value

Paketleme :

- 10 pieces in the box
- Dimensions of the box: 126 mm * 44 mm * 180 mm
- Box weight: 100 gr.
- It is produced in various colours.

FISH MASK : MODEL NO : OP-MASK-0210

It is designed to protect against solid and non-volatile liquid particles.

Technical Specifications :

- Fish mask is the product name.
- Op-Mask-0210 is the model number.
- Production is made to the EN 149:2001 standard.

Packaging :

- 10 pieces in the box
- Dimensions of the box: 126 mm * 44 mm * 180 mm
- Box weight: 100 gr.
- Colour: Various colours can be produced





Innovation Health & Medical



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