

Instructions for Use Medical Face Mask



Before using product, please read all information carefully

⚠ This mask helps to protect against certain particulate contaminants but does not eliminate exposure to or the risk of contracting any disease or infection.

Misuse may result in sickness or death.

Notice in case of any serious incident please report it to the manufacturer and your competent authority.

Before use, the wearer must read and understand these User Instructions. Keep these instructions for reference.

1. PRODUCT NAME

Medical Face Mask

2. DESCRIPTION/INDICATIONS

Medical face mask is a medical device covering the mouth and nose providing a barrier to minimize the direct transmission of infective agents between staff and patient. Transmission of fluid-borne agents from patients to staff may occur via splashes.

Intended Purpose

This product meets European Standard EN 14683, Type IIR.

As a medical face mask, it is intended to provide a barrier to minimize the direct transmission of infective agents between staff and patient. It is designed to be fluid resistant to splash and spatter of blood and other infectious materials.

Medical face masks may also be intended to be worn by patients and other persons to reduce the risk of spread of infections, particularly in epidemic or pandemic situations.

3. SPECIFICATION

This medical face mask is Type IIR mask acc. to EN 14683.

Table 1 — Performance requirements for medical face masks

Testavimas	Tipas I	Tipas II	Tipas IIR
Bakterinio filtravimo efektyvumas (BFE) %	≥95	≥98	≥98
Differential pressure (Pa/cm ²)	<40	<40	<60
Splash resistance pressure (kPa)	Not required	Not required	≥16,0
Microbial cleanliness (cfu/g)	≤30	≤30	≤30

4. CONTRAINDICATIONS

This product is not a respirator device which is applicable in accordance with the Personal Protective Equipment (PPE) Directive (89/686/EEC) or the Personal Protective Equipment (PPE) Regulation (EU) 2016/425. Performance requirements for respirators are the scope of EN 149.

Do not use the medical face mask for respiratory protection for the wearer.

This mask is not intended for industrial use.

5. CAUTIONS and WARNINGS

- Inspect mask before the use to ensure that it is in good operating condition. Examine all the mask parts for signs of damage including the two ear loops, nose clip and facepiece material.

- Ensure there are no holes in the breathing zone and no damage has occurred.

- Avoid touching the inside of the mask with your hands.

- If you are concerned about the smell of the mask or feel it hard to breathe or feel

nauseous, pls stop using immediately.

- If itching, spot rash or other symptoms occur, please stop using immediately.
- Discard after every use when the mask is used for surgical procedures. Follow national, state, local and facility infection control guidance and policies.
- Change the mask timely. In general, surgical mask should not be reused. Replace the mask immediately if it is damaged or soiled, breathing becomes difficult or contaminated with blood or body fluids.
- The mask should be disposed of immediately upon observation of damage or missing parts.
- Dispose of used product in accordance with applicable regulations.
- This is single-use device. A reprocessing and re-use of the device is not allowed. An infection or transmission of diseases could occur, if the device were to be re-used.

6.DIRECTIONS FOR USE

- Open the package and take out the mask;
- Flatten the mask, with the blue side facing outwards, and push with both hands to the face with the nose clip uppermost;
- For tie-on mask, secure upper ties at the crown of head. Then secure lower ties at the nape. For ear-loops type, position the elastic bands around both ears. Press the bendable nose clip gently to make the mask close to the face;
- Pull up and down the edge of the mask with both hands so that it covers under the eyes and chin.

7.STORAGE

Keep away from sunlight.

Avoid excessive heat.















8.SHELF LIFE

2 years.

9.PRODUCT DISPOSAL

After use, this product may be a potential biohazard. Handle and dispose of the device in accordance with accepted medical practice and applicable local, state and federal laws and regulations. Contaminated products should be disposed as hazardous waste in accordance with national regulations.

10.EXPLANATION OF SYMBOLS USED ON LABELS AND INSTRUCTIONS FOR USE:

	Do not re-use		Keep dry
	Keep away from sunlight		Consult instructions for use
	Do not use if package is damaged		Non-sterile
	Caution		Batch Code
	Not made with natural rubber latex		Manufacturer
	Use-by date		Catalog Number
	Authorized representative in the European Community		Date of manufacture



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