

1. GENERAL INFORMATION ON THE DEVICE

Type	Single-use non-sterile SMS face mask
Classification pursuant to Annex IX Leg. Decree 46/97	Class I non-sterile and without a measuring function
Classification pursuant to UNI EN 14683:2019	Type II
Model	A3 - MIROGLIO SURGICAL FACE MASK
Year of production	2020
CND (Italian Classification of Medical Devices)	T020699 - SURGICAL FACE MASKS - OTHERS

MANUFACTURER

Business name	Miroglio Textile s.r.l.
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Photo of the medical device:

2. DESCRIPTION OF THE MEDICAL DEVICE

The **A3 MIROGLIO SURGICAL FACE MASK** medical device is a **single-use SMS face mask classified as a Class I non-sterile medical device with no measuring function** pursuant to section III of Annex IX to Directive 93/42/EEC, and **Type II** pursuant to the UNI EN 14683:2019 Standard, therefore it does NOT offer protection against the risks associated with splashes of hazardous liquids.

General characteristics

- White half-face mask, not fitted with an exhalation valve, covering the mouth, nose and chin;
- Guarantee of ample field of vision, effective adherence to face and appropriate level of comfort thanks to the ear elastics heat-sealed to the mask's filtration fabric.

Materials

The A3 MIROGLIO SURGICAL FACE MASK is made of two layers of non-woven fabric, held together by a heat-sealed non-woven fabric ribbon to ensure greater comfort. The two layers are as follows:

1st Layer: 80g 100% SMS

2nd Layer: 80g 100% SMS

Applications

The M 01 CE medical device must only be used by people and/or in work settings requiring a level of face mask protection which is NO higher than type II according to UNI EN 14683:2019.

Dimensions

175 x 95 mm

3. INSTRUCTIONS FOR WEARING THE MEDICAL DEVICE

How to put on the face mask:

1. Before putting on the face mask, wash your hands with soap and water or an alcohol solution;
2. Make sure the mask is complete, and has no holes, tears, etc.
3. Open up the mask, with the rigid part at the top;
4. Hold the mask by the elastics, and hook them behind your ears;
5. Pull the mask from the top and bottom to open the folds and stretch it over your face;
6. Mould the mask over your nose so it adheres to your face.

**While wearing the face mask, avoid touching it with your hands.
If it is absolutely necessary to touch the mask, wash your hands beforehand and afterwards.**

How to remove the mask:

1. Before taking off the mask, wash your hands with soap and water or an alcohol solution;
2. Avoid touching the mask with your hands; it could be contaminated;
3. Hold the mask by the ends of the elastics, and unhook them from behind the ears;
4. Proceed with the disposal of the mask as instructed below;
5. Wash your hands with soap and water or an alcohol solution after touching the mask.

4. STORAGE AND DISPOSAL

Method of storage

- Store the masks in their original packaging in a clean, dry place, away from direct sunlight, sources of high temperature and solvent vapours.
- Store at a temperature of between -10°C and +30°C, and relative humidity of less than 80%.
- The shelf life is three years following the date of production (referred to new, packaged product).
- Replace the product if it is damaged or contaminated, or as provided for by working practices or local legislation.

Method of disposal

The A3 MIROGLIO SURGICAL FACE MASK medical device is designed and made to be used in one continuous work shift, at the end of which it can no longer be used and must be disposed of as sanitary waste.

The material used for the packaging of the sales units is fully recyclable, and is to be disposed of pursuant to Legislative Decree 152/06 for those involved in business operations. and by private citizens as provided for by local recycling procedures.

5. LIMITATIONS TO THE USE OF THE DEVICE

THE A3 MIROGLIO SURGICAL FACE MASK MEDICAL DEVICE IS NOT A PIECE OF PERSONAL PROTECTIVE EQUIPMENT PURSUANT TO LEGISLATIVE DECREE 475/92 AS AMENDED BY LEGISLATIVE DECREE 17/2019 AND REGULATION (EU) 2016/425

THE A3 MIROGLIO SURGICAL FACE MASK MEDICAL DEVICE DOES NOT PROVIDE PROTECTION FROM SPLASHES OF POTENTIALLY CONTAMINATING LIQUIDS

THE A3 MIROGLIO SURGICAL FACE MASK MEDICAL DEVICE IS NOT A STERILE PRODUCT AND IS NOT REUSABLE

6. WARNINGS AND PRECAUTIONS

Before its use, make sure that the **A3 MIROGLIO SURGICAL FACE MASK** medical device is suitable for the application and/or working environment in which it is intended to use it, and that it is worn correctly. **DO NOT** modify or alter the face mask in any way. **DO NOT** use the face mask in any way other than that which is intended by the manufacturer.

THE FOLLOWING ARE ABSOLUTELY PROHIBITED:

- Use of the face mask as a piece of personal protective equipment;
- Use of the medical device by anyone who has not read these instructions for use carefully;
- Use by anyone allergic to the substances the product is composed of;
- Use by children, unless expressly permitted by the laws in force in the country the mask is to be used in;
- Use by anyone with respiratory conditions and/or other health conditions which are incompatible with the use of the mask;
- Wearing the mask during sporting and/or motor activities requiring a certain amount of physical effort;
- Wearing the mask with the outside facing towards the mouth after wearing it correctly;
- Wearing the mask continuously for more than 8 hours without changing it;
- Wearing the mask while riding a bicycle or driving another vehicle which requires a certain amount of physical effort;
- Applying the mask to damaged skin or onto a wound;
- Cleaning and disinfecting the mask in order to wear it again or give it to someone else to wear;
- Smoking or drinking through the mask;
- Applying the medical device to other parts of the body.

Collateral effects

There are no side effects to report in relation to the use of the **A3 SURGICAL FACE MASK** medical device.

However, it is **NOT** advisable to apply the product to skin in the event of lesions or inflammation. If the product causes any irritation, suspend its application immediately and consult a doctor.

Contraindications

DO NOT use the **A3 SURGICAL FACE MASK** medical device if you are allergic to the materials used to make it as described herein in section 2 under "Materials".

The information contained in this document may be subject to revision at any time.