

## MANUFACTURER'S DATA

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**AUTHORIZED SERVICE:** Assistance on medical devices may be provided exclusively by authorized and qualified staff of Tramonte S.n.c. Firm

## PRESENTATION OF THE MANUAL

This manual includes instructions for the use of the washable mask. The manual is composed of different sections, each dealing with a series of topics, divided in chapters and paragraphs.

The general index lists all the topics dealt in the whole manual. This manual is addressed to the user in charge of the employment and conservation of the medical device and regards technical life after its production and sale.

This manual includes proprietary information and can't be even partially passed to a third party for any use and any form, without the previous written consent of the manufacturer.

Tramonte S.n.c. declares information included in this manual is congruent with the specific safety techniques of the medical device the manual refers to.

Certified copy of this manual is included in the device operative dossier, kept at Tramonte S.n.c. at the Operational Headquarters located in Bojon di Campolongo Maggiore (VE) Via II° Strada, 10











Tramonte S.n.c. doesn't recognise any documentation which hasn't be produced, issued or distributed by itself or by one of its authorized representatives.

This manual, as well as the whole technical dossier, will be kept by the manufacturer for the period prescribed by law.

In this period copy of documentation accompanying the product may be requested, at the time of sale.

The whole technical dossier will be available for this period only to the supervisory authority, who may ask copy of it. After this period, it will be the one who manages the product's duty and care to verify that both the product and documentation respect the laws in force, in order to be able to use it according to the existing legislation.

## SYMBOLGY DM

	Lot number		Latex Free Product
	Date of manufacture		Protect from moisture and from atmospheric agents
	Manufacturer		Protect from direct sunlight
	Read the manual before using it		Recyclable Packaging Box
	CE Brand		Expiry date

## WARRANTY

Warranty terms, completely listed in the purchase contract, are valid only if the medical device is utilized according to its intended use. Any restoration and modification made to the device by the user or by unauthorised companies determines the voidance of warranty. The warranty does not extend to damages caused by incompetence or negligence in the use of the device.

I prodotti da noi venduti sono coperti da garanzia per quanto riguarda le seguenti condizioni:

- The warranty is valid for a period of twelve (12) or twenty-four(24) months depending on the legal nature of the purchaser.
- The Manufacturer commits to replacing at its own discretion faulty products, only after a careful control and evidence of poor construction, provided that the product is complete with labels.
- Transport and/or shipping costs in case of incorrect use of warranty terms will be still charged to the purchaser.
- In the warranty period the parts replaced will become the producer's property.
- Only the original purchaser who has respected the indications of a regular use included in the manual can benefit from this warranty. Our liability on the warranty expires at the moment when the original owner transfers the property of the device, or modifications have been made to the it.
- The warranty doesn't include damages caused by excessive strain such as the use of the device after anomaly finding, by the incorrect or inappropriate use as well as by the the failed observation of the operating instructions.
- The manufacturer will not accept any responsibility for possible difficulties coming from the resale or the use abroad due to the regulations in force in the Country where the medical device has been sold.

**Warning:** whereas the use of the warranty might be considered necessary, please leave the following:

- The data reported on the label sewn on the item and the data reported on the adhesive external label.
- Date of purchase (presentation of the purchase document)
- Detailed description of the problem

## DESCRIPTION OF THE MEDICAL DEVICE

The medical devices subject of the following technical dossier are masks made layering washable textile material intended for being used by medical and nursing staff to protect themselves and patients during operations which might put them at risk. The mask is a mechanical barrier against material and substances. The mask as a matter of fact is necessary to avoid contamination from and to the patient and to protect the respiratory tract from dust, spray and other material which is used during medical activity. The medical device is not sterile and reusable.

## EXPIRY DATE

The product has a 5-year expiry date from the production date exclusively if not used and kept close in the original packaging protected by the adhesive closure with the device date reported and kept according to the instructions.

**TECHNICAL DATA****Material used for the mask**

The device is produced with a series of layers composed of a part of pure cotton in contact with skin, a central gap of 4mm (+10%) in Polyester which acts as a filter and helps the evaporation of condensation and another protective external layer, to this some profiles ending with two stretch cotton laces to fasten on your ears are added. **Average weight gr. 11 (+/- 10%)**, It can be produced in different colours and sizes S/M e L/XL

**Field of application and intended use**

The medical device is to be used in order to avoid contaminations to the patient.

**Non-intended use**

Any use different from those described in the paragraph “**Field of Application and intended use**” is non-intended.

Moreover it is totally forbidden: the use of the mask as device of individual protection, the use of medical use by subjects who haven't read the manual carefully, the use by allergic subjects to the substances the product is made of, the use by children, the use of the device for applications in contrast to those listed in “**Field of Application and intended use**”, apply the mask on injured skin or on a wound, apply the medical device on body parts other than your face.

**Limits of the medical device:** masks don't cure any disease.

**RESIDUAL RISKS**

It is totally forbidden make any modifications to the medical device. Any damage coming from the use of the device, improperly modified by an unauthorized operator, relieves the Manufacturer from any responsibility. Keep this manual with care, necessary for a correct and safe use of the medical. In case the device structure presents deformations due to an accidental impact, as friction against abrasive material, to such an extent to make it or assume it dangerous and/or unusable, it is necessary to contact the authorized service and follow their instructions.

**Side effects**

There are no side effects to point out in the manual of instructions. Yet, don't apply the product in case on your skin when a wound or rash is present.

In case of rash caused by the product, immediately stop the application and contact a doctor.

**Contraindications**

The medical device might cause rashes on subjects particularly sensitive or allergic to the material it is made of. Don't use it if you are allergic to cotton, polyester, polyamide, elastan fibres.






**Use instructions**

- Open the packaging
- Sanitise your hands washing them thoroughly with specific products.
- Take the mask out of the package.
- Put the mask on taking care to cover, and keeping covered in use, your nose and mouth, placing the elastic drawstring behind your ear to hold it on your face.

**WASHING INSTRUCTIONS**

The device is designed to be washed several times, and so reused 15 times at least, only if washing instructions on the label sewn on it are followed. It is recommended to use the device not more than 4 consecutive hours and not more than 8 hours per day. In the event of the operator's heavy work, anyway when breathing is heightened, and generally speaking in conditions of elevated sweating, it is recommended to stop activity for some minutes and apply the mask in such a way that the possible excess moisture on your breathing tract, can evaporate.

**WASHING SYMBOLS REPORTED ON THE LABEL ON THE ITEM**

	Lavare il prodotto a mano in acqua a temperatura non superiore a 40° con detersivi neutri e non aggressivi.
	Non candeggiare
	Non mettere in asciugatrice
	Stirare con ferro tiepido
	Non lavare a secco

**Handwash the product in lukewarm water not hotter than 40° with neutral and mild detergents**

**Don't bleach**

**Don't put in the dryer**

**Iron with a lukewarm setting**

**Don't dry clean**

**PRESERVATION**

Before preserving the medical device please check it is clean.

- The mask if kept in its packaging, unused, properly preserved according to instructions, has a 5-year expiry date from the manufacture date.
- Keep the medical device in cool interior, far from atmospheric agents and steam jets.
- Keep the medical device far from heat sources, free flames and from the direct sunlight.
- After use, place the washed and totally dried mask in a container, safe from direct sunlight, from atmospheric agents, heat sources, dust, liquids and moisture.
- Keep out of reach of children.
- Don't bring heat sources close to it.

**DISPOSAL**

At the end of the use of the medical device ensure its disposal.

The construction materials of medical devices don't need special disposal procedures. It is necessary to make reference to local rules about unsorted waste disposal.

Do not scatter or leave the product in the environment for any reason.