o-range CARE: Reusable, surgical face mask type II EN 14683

Our masks are made combining two kinds of fabric, optimized for filtering capability – equivalent to a medical face mask of type II – and comfort alike.

Furthermore, the masks are realized with an elastic and non-run fabric body, for better adherence to the skin and smoother wearability. The central area, containing mouth and nose, is made of a triple layer of filtering fabric, which is then united to the mask's body.

The outer fabric layer has been tested against noxious substances and is certified "Oeko-Tex standard 100"

Bacterial Filtration Efficiency (BFE) > 98%

Composition:

- Body: 68% PA Polyamide – 32% EA Elastane

- Filter: 100 % PP Polypropylene

HOW TO USE THE FACE MASK

The face mask is made of a firm part over the nose and two holes on the sides, which have to be applied around the ears to keep the mask in place.

The filtering area is located at the innermost layer of the mask, in contact with the mouth.

Stretch the elastic fabric until the ear is covered

LAYERS

- 3 Layers of filtering fabric

INSTRUCTIONS AND PRECAUTIONS

Handle the mask only after cleaning your hands, avoid touching the inner filter.

HOW TO STORE THE FACE MASK

Keep the product in a dry, temperate place. Don't store in an environment with temperatures higher than 40°C.

Don't expose to direct sunlight, UV light and fluorescent lamps. If the packaging is damaged, don't use the product. Don't use the mask beyond the expiration date marked on the packaging.

WASHING THE PRODUCT

Details:

The mask's filtration capacity remains unaltered even with 8 washing cycles.

<u>1st STAGE – HAND WASHING THE PRODUCT:</u>

Hand washing the mask using a mild detergent is advised. Don't dry the product in direct sunlight.

<u>2nd STAGE – RECONDITIONING WITH HYDRO-ALCOHOLIC SOLUTION:</u>

After the treatment, reconditioning with hydro-alcoholic solution is advised:

Thoroughly clean your hands.

Avoid touching the mask in its innermost filter area.

Wear a new pair of single-use gloves or alternatively sanitize the hands with a hydro-alcoholic solution (75-85%).

Lay the mask down on a previously-cleaned or sanitized surface, again employing the hydro-alcoholic solution (75-85%).

Spray the hydro-alcoholic solution (75-85%) evenly on the entire fabric, without using too much: it's sufficient to apply an even layer of solution on the entire surface of the fabric.

Turn the mask around and repeat the aforementioned step.

Leave the mask to rest in a protected environment until the entire drying process is completed (at least 30 minutes, although the elapsed time may vary with different environmental conditions).

After the drying is completed, and the time mentioned is passed, the mask is to be considered sanitized. Therefore, avoid to contaminate it, particularly in its innermost filter area.

3rd STAGE – RINSING:

Rinsing the product with fresh water is advised, in order to remove all the remaining hydro-alcoholic solution.

PRODUCT DETAILS

REUSABLE SURGICAL FACE MASK TYPE II

Rev. 03

May, 2020

code:	name:
OR 2020	O-RANGE MASK

Material: THREE LAYERS OF FILTERING FABRIC (Spun bond – Melt blown – Spun bond)	
Manufacturer	Orange s.r.l. TV Italy
OR 2020	Surgical Face Mask type II in compliance with UNI EN 14683 EC class 1 marking (Annex XIV - Rule 1) in compliance with Council Directive 93/42/EEC.

DESCRIPTION

Multiple-layer, reusable surgical face mask equipped with in an external Lycra layer coupled with non-woven fabric across 3 layers, produced with **SMS loaded with mass of Meltblown to perfect filtration**.

The crafting process, which has been patented, guarantees a great wearability of the product, which results in a well-fit mask; the product is to be fit to the face utilising the two eyelets, embodied in the mask's Lycra fabric.

The filtering fabric, opaque PA Polyamide, which is odorless, breathable, soft, hypoallergenic, durable, devoid of adhesive resins and glass fibre, retains good permeability.
Latex-free. The mask is heat-sealed.

STERILITY

The O-RANGE MASK is not a sterile product.

SHELF LIFE

5 years.

PACKAGING

Code	Folded mask size (mm)	Standard mask size(mm)	Bag size (N° pieces)
OR 2020 - S	155 x 70 x 2	300 x 150 x 1	10
OR 2020 - M	165 x 70 x 2	305 x 160 x 1	10
OR 2020 - L	170 x 70 x 2	315 x 165 x 1	10

CHEMICAL COMPOSITION

Elastic body composition: 68% PA - Polyamide, 32% EA - Elastane
Filter composition: 100 % PP Polypropylene

TECHNICAL SPECIFICATIONS AND DESCRIPTION	PCS.	MATERIAL	WEIGHT	WEIGHT TOLERANCE	CHARACTERISTICS
External Fabric	1	Elastic, non-run fabric 68% PA (Polyamide) 32% EA (Elastane)	218 gr/ m^2	± 5%	Stability washing machine 40° (ISO 5077)
Filtering Fabric	3	**SMS caricato con massa di Melt-blown** 7gr/m^2 100% PP (Polypropylene)	35 gr/ m^2	± 5%	Breathable, Hypoallergenic, Traction-Resistant(MD 70/5cm), Non-run fabric
Assembly					Heat-seal

PHYSICAL-CHEMICAL PROPERTIES OF POLYPROPYLENE USED FOR THE FABRICATION OF THE FILTERING LAYER	
State	Solid
Color	White/Green
Smell	None
Melting point	160° C
Flammability	Not available
Self-ignition	Not available
Weight	35 g/m2 - tolerance ± 5%
Traction resistance (MD)	N/5cm 70

Traction resistance (CD)	N/5cm 42
Stability	Stable in normal conditions
Reactivity	Material not compatible with strong, concentrated acids
Environmental friendliness	Non-biodegradable

QUALITY CONTROL

TEST	REFERENCED REGULATION	RESULT
BACTERIAL FILTRATION EFFICIENCY BFE (%)	EN 14683, ASTM F 2101-07	FILTERING EFFICIENCY > 98%
AIR PERMEABILITY (Pa/cm2)	EN 14683, ASTM D 737	DIFFERENTIAL PRESSURE < 37 Pa/cm2
MICROBIAL CLEANLINESS(cfu/g)	EN 14683, EN 11737-1	**15 C.F.U./g**
LATEX PARTICLE CHALLENGE	ASTM F 1215 – ASTM F 2100-01	FILTERING EFFICIENCY > 98,5%

ENVIRONMENTAL FRIENDLINESS

According to the legislations ISO 10993-1 the product has been tested for its biocompatibility with the following materials:

skin contact, mucous membranes, injured or compromised surfaces, prolonged contact time.

HIGH-LIGHTED DEFECTS	LEGISLATION	VERIFICATION METHOD	SAMPLING METHOD	ACCEPTABLE QUALITY LEVEL
Cytotoxicity	ISO 10993-5	In vitro	random	Environmentally-friendly
Sensitization	ISO 10993-10	In vitro	random	pending
Irritation	ISO 10993-10	In vitro	random	pending

PRODUCTION PROCESS

1- Raw material, composed from non-woven fabric and elastic fabric, once the quality checks have been passed, are assembled, cut, and heat-sealed. The fabric is cut using laser for maximum precision.
2- The finished product is checked, sorted and packaged in 10-PCS polyethylene bags.
3- During the preparation for shipping, before it is packaged inside its cardboard box, the product in checked once again.

INSTRUCTIONS FOR STORING AND STOCKPILING

Keep the product in a dry, temperate place. Don’t store in an environment with temperatures higher than 40°C.

Don’t expose to direct sunlight, UV light and fluorescent lamps. If the packaging is damaged, don’t use the product. Don’t use the mask beyond the expiration date marked on the packaging.

MEANS OF DISPOSAL

The masks can not be recycled, therefore they are to be disposed of as unsorted waste according to the law. They can be incinerated without forming toxic waste.

HOW TO USE AND OPERATIONAL ADVICE

PLEASE NOTE:

Such a treatment is discouraged for personnel operating with infected people (or in an environment with a high danger of infection) as at the moment there is not sufficient data for proving its effectiveness.

Please remember that both the exterior of the worn mask and hands/gloves can me contaminated by the virus; as such, particular care must be applied while handling it, in order to avoid infection or re-infection. It is imperative to follow the directives in the order described below, to avoid contamination.

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Avoid touching the mask in its innermost filter area.

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