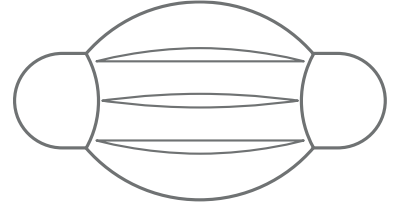


## Technical Data Sheet

### OPERO mask – 3 ply surgical mask type IIR, with earloops



#### PRODUCT DESCRIPTION

<b>Type of the product</b>	3-ply surgical face mask, with earloops, made from non-woven, non-dusting. Soft wire embedded in plastic ensures that mask fits properly to the user's face. Product non sterile, for single use.		
<b>Intended use</b>	Medical device (surgical mask type IIR) covering mouth and nose, constituting a barrier that minimizes direct transfer of infectious agents between staff and the patient, and to limit the transfer of microorganisms and bacteria to the surgical wound during surgery, which limits possibility of wound infection and reduces the risk of postoperative complications. . For use during surgical procedures. For use by qualified personnel (professional users). Single-use product, non sterile.		
<b>Material &amp; weight</b>	Inner layer	Spunbond (Polypropylene)	20 g/m <sup>2</sup> ± 2 g/m <sup>2</sup>
	Middle layer	Meltblown (Polypropylene)	25 g/m <sup>2</sup> ± 2 g/m <sup>2</sup>
	Outer layer	Spunbond (Polypropylene)	25 g/m <sup>2</sup> ± 2 g/m <sup>2</sup>
<b>Type of ear loops</b>	Latex free		
<b>Type of joining each layer and ties together</b>	Ultrasonic sealing		
<b>Type of face mask</b>	Type II R (according to EN 14683)		
<b>Color of the outer mask layer</b>	Blue		
<b>Packaging</b>	50 pcs / box; 2000 pcs / carton		

#### PRODUCT REFERENCES

<b>Color / Reference Number</b>	Blue	W413110030_0028
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#### PHYSICAL PROPERTIES

		Tolerance [cm]	
<b>Dimensions</b>	Width of the face mask [cm]	9.5	± 0.5
	Length of the face mask [cm]	17.5	± 0.5
	Length of the nose wire [cm]	10.5	± 0.5
	Length of each earloop [cm]	17.0	± 1.0

#### PERFORMANCE PARAMETERS

<b>Parameters acc. to EN 14683 standard</b>	Bacterial Filtration Efficiency (BFE)	≥ 98%
	Differential Pressure	< 40 Pa/cm <sup>2</sup>
	Microbial Cleanliness	≤ 30 CFU/g
	Splash Resistance Pressure	≥ 120 mm Hg ( 16 kPa )

#### MANUFACTURING AND SAFETY STANDARDS

<b>Classification</b>	<b>Medical Device: CE</b> class I (Regulation (UE) 2017/745)
<b>Compliance with product standards</b>	EN ISO 15223-1, EN ISO 20417, EN ISO 14971, EN 14683
<b>Compliance with quality standards</b>	EN ISO 13485, ISO 9001
<b>REACH</b>	Product does not contain any of the chemical listed in the REACH "Candidate List of Substances of Very High Concern" according to REACH Regulation (EC) No 1970/2006.

#### STORAGE AND DISPOSAL

<b>Long-term storage instructions</b>	It is recommended to store product in dry place, in the temperature of 5-30°C and to protect them against direct sunlight. Keep products in a distance of not less than 1m from heating devices, sources of fire and ozone.
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**Transport instructions**

Transport in conditions ensuring an appropriate hygienic standard, protecting the product against dirt. The product is not thermolabile - changing conditions regarding temperature or humidity in the short-term transport period do not affect the usability of the product or its properties or safety of use in any way. The product does not require transport in controlled conditions in terms of temperature and humidity (confirmed on the basis of accelerated aging tests and risk analysis).

**Shelf life**

5 years from the manufacturing date.

**Disposal of product**

If product has been used - must be disposed of as a contaminated product.

**Disposal of unit packing and transport carton**

Packaging made of homogeneous material, does not contain different types of material, does not need to be separated into fractions. Packaging is 100% recyclable, in accordance with local regulations.