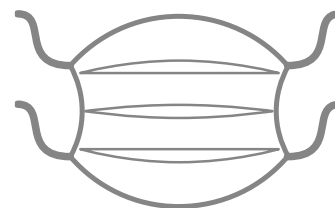


Technical Data Sheet

OPERO mask – 3 ply surgical mask type IIR, with ties



PRODUCT DESCRIPTION			
Type of the product	3-ply surgical face mask, with ties, 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.		
Intended use	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.		
Material & weight	Inner layer	Spunbond (Polypropylene)	20 g/m ² ± 2 g/m ²
	Middle layer	Meltblown (Polypropylene)	25 g/m ² ± 2 g/m ²
	Outer layer	Spunbond (Polypropylene)	25 g/m ² ± 2 g/m ²
Type & color of ties	White	Spunbond (Polypropylene)	35 g/m ² ± 2 g/m ²
Type of joining each layer and ties together	Ultrasonic sealing		
Type of face mask	Type II R (according to EN 14683)		
Color of the outer mask layer	Blue		
Packaging	50 pcs / box; 40 boxes (2000 pcs) / carton		

PRODUCT REFERENCES		
Color/ Reference Number	Blue	W413110030_0028

PHYSICAL PROPERTIES			
Dimensions			Tolerance [cm]
	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 tie [cm]	40.0	± 3.0

PERFORMANCE PARAMETERS			
Parameters acc. to EN 14683 standard	Bacterial Filtration Efficiency (BFE)	≥ 98%	
	Differential Pressure	< 60 Pa/cm² (according to EN 14683:2019+AC:2019)	≤ 300 Pa (according to EN 14683:2025) ¹
	Microbial Cleanliness	≤ 30 CFU/g	
	Splash Resistance Pressure	≥ 120 mm Hg (≥ 16 kPa)	
	¹ The previous version of this standard contained a mathematical error in the way pressure differential was calculated. This has been corrected in the new version and resulted in a change to the units used for the test in Annex C and the limits for medical masks in Table 1. The change means that the units are now the standard SI unit (Pa instead of Pa/cm²), and the limits have been multiplied by the test area (4.9 cm²) to return to the standard SI units. Manufacturers can still compare tested medical masks with results from the previous edition of this document by multiplying their old test results by 4.9.		

MANUFACTURING AND SAFETY STANDARDS	
Classification	Medical Device: CE class I (Regulation (UE) 2017/745)
Compliance with product standards	EN ISO 15223-1, EN ISO 20417, EN ISO 10993-1, EN ISO 10993-5, EN ISO 10993-10, EN ISO 14971, EN 14683

Compliance with
quality standards

EN ISO 13485, ISO 9001

REACH

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

Long-term storage
instructions

It is recommended to store product in dry place, in the temperature of 5-40°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.

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 packaging
and transport carton

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.



Packaging for disposal - throw into the blue container