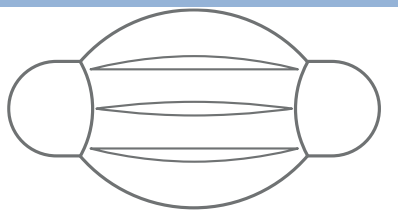
MERCATOR

Technical Data Sheet

OPERO 3-ply non-woven face mask with ties



PRODUCT DESCRIPTION

Type of the product	3-ply non-woven face mask, with earloops, 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	A medical device (medical mask type II) covering mouth and nose, constituting a barrier, that minimizes direct transfer of infectious agents between staff and patient, and to limit transfer of microorganisms and bacteria to the surgical wound, which limits possibility of wound infection, and reduces risk of postoperative complications, or generally reduces possibility of transmitting pathogenic microorganisms. For use during surgery and other medical settings with similar requirements. For use by qualified personnel (professional users). Single-use product, non sterile.		
Material & weight	Inner layer	Spunbond (Polypropylene)	25 g/m² ± 2 g/m²
	Middle layer	Meltblown (Polypropylene)	25 g/m² ± 2 g/m²
	Outer layer	Spunbond (Polypropylene)	25 g/m² ± 2 g/m²
Type of joining each layer and ties together	Ultrasonic sealing		
Type of face mask	Type II (according to EN 14683)		
Color of the outer mask layer	Blue / green / white		
Packaging	50 pcs / box; 2000 pcs / carton		

PRODUCT REFERENCES

Color / Reference Number	Blue	W411100030_0028
	Green	W411200030_0028
	White	W411300030_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 earloop [cm]	17.0	± 1.0

PERFORMANCE PARAMETERS

Parameters acc. to EN 14683 standard	Bacterial Filtration Efficiency (BFE)	≥ 98%
	Differential Pressure	< 40 Pa/cm²
	Microbial Cleanliness	≤ 30 CFU/g
	Splash Resistance Pressure	Not applicable

MANUFACTURING AND SAFETY STANDARDS

Classification	**Medical Device: CE** class I (Regulation (UE) 2017/745)
Compliance with product standards	EN ISO 15223-1, EN 1041, ISO 10993-1, ISO 10993-5, 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 5-30°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.
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.