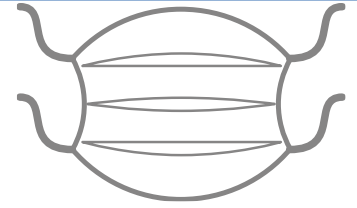


Technical Data Sheet

Opero® 3-ply non-woven face mask with back ties



PRODUCT DESCRIPTION			
Type of the product	3-ply non-woven face mask, with back ties, 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	Mask prevent infection and surface contamination. Due to the high air permeability, they allow easy breathing and at the same time provide a high filtration barrier. They are equipped with an insert that allows for exact matching to the shape of face, thus guaranteeing maximum protecting.		
Material & weight	Inner layer	Spunbond (Polypropylene)	25 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
	Ties	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 (according to EN 14683)		
Color of the outer mask layer	Blue / green / white		
Color of the ties	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 tie [cm]	40.0	± 3.0

PERFORMANCE PARAMETERS		
Parameters acc. to EN 14683 standard	Bacterial Filtration Efficiency (BFE)	≥ 98%
	Differential Pressure	< 40 Pa/cm ²
	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	
Storage instruction	Keep out of direct sunlight. Store in a cool, dry place in temperature 5 - 30°C.
Shelf life	5 years
Disposal	Follow local instructions.