

### 1. Identification of the product and manufacturer

#### 1.1. Product identification

Product name: PRAESIDIUM medical mask  
TYPE: IIR  
Product class: I, non-sterile product  
UDI code: 3661812RDB

#### 1.2. Manufacturer's data

Company: TW PLAST Sp. z o.o.  
ul. Puławska 38  
05-500 Piaseczno  
Phone number: +48(22) 750 00 80  
E-mail address: office@twplast.pl

### 2. General information



Disposable medical masks, non-sterile. They are designed to protect the patient against infections, and under certain circumstances to protect the user from potential splashes of contaminated fluids. Medical face masks may also be designed to be worn by patients and others to reduce the risk of the spread of infection, particularly in epidemic or pandemic situations..

### 3. Information on the composition of the product

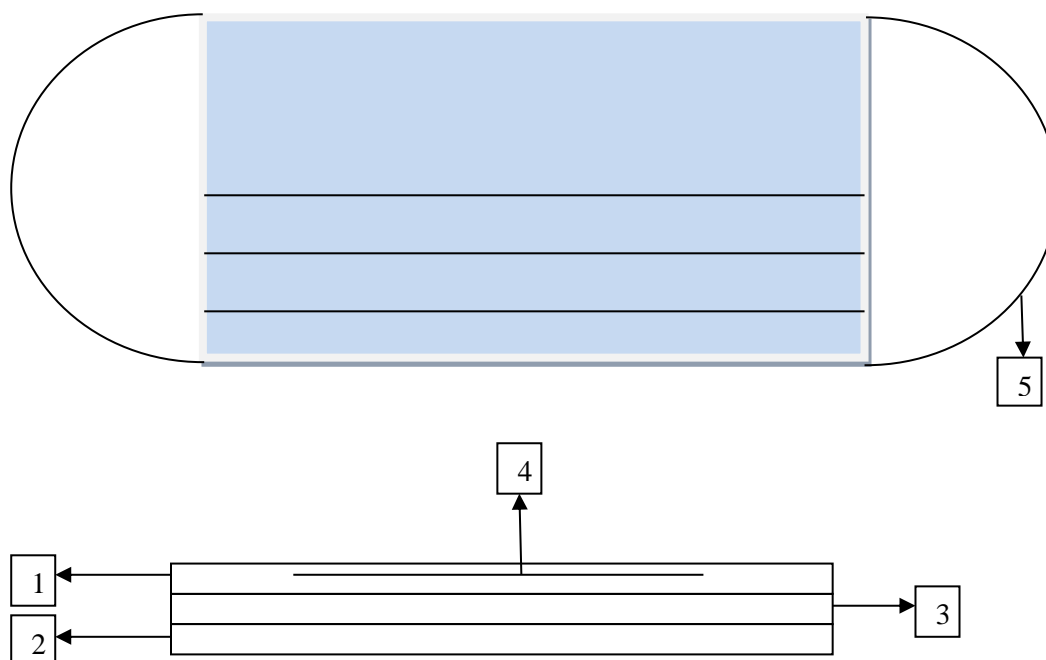
Part of the mask	Composition
Outer layer	Polypropylene (spunbond nonwoven fabric) with increased resistance to splashes
Filter layer	Polypropylene (meltblown nonwoven fabric)
Inner layer	Polypropylene (spunbond nonwoven fabric)
Nose wire	Galvanized in a polyethylene braid
Elastic ear loops	Core: SPANDEX (polyurethane), sheath: polyester

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#### 4. Technical parameters of the product

**Dimensions: 17,5 cm x 9 cm**



Mask construction: 1 - outer layer (polypropylene spunbond nonwoven fabric); 2 - inner layer (polypropylene spunbond non-woven fabric); 3 - filter layer (meltblown polypropylene non-woven fabric); 4 - metal wire; 5 - elastic bands.

#### Tests - were performed in accordance with the PN-EN 14683: 2019 standard



No.	Test	Unit	Standard requirement	The result obtained
1.	Differential pressure	[Pa/cm <sup>2</sup> ]	< 60	42,02
2.	BFE bacteria filtration capacity	[%]	≥ 98	99,9
3.	Splash resistance pressure (ISO 22609)	kPa	≥ 16	16*
4.	Microbiological purity	[cfu/g]	≤ 30	2,4
5.	Cytotoxic action	-	No cytotoxic effect	Wloknipol-M® - PP Nonwovens meeting the requirements of the STANDARD 100 by OEKO -TEX® standard, Annex 6 - product class I - certificate no. IW00096 of 04/03/2020, test report no. NC9046 / 08/2020
6.	Irritating effect	-	No irritating effect	
7.	Sensitizing effect	-	No sensitization	

\*) According to ASTM F1862 and ISO 22609, the acceptable quality limit of 4.0% is met on the sampling plan when ≥29 of 32 test articles show positive results.

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### 5. Storage conditions

The products should be stored at a temperature of 5 ° C - 45 ° C and humidity of 25% - 65%, protected against sunlight.

DEVELOPED	APPROVED
 24.11.2020 Jacek Radziejewski	 24.11.2020 Sławomir Woźniak