

TECHNICAL FILE FOR DEVICE:

MEDICAL 3-LAYER DISPOSABLE FACE MASK TYPE I and II

General Description

Medical 3-layer masks, latex free, fiber glass free, hypo-allergic, with ear loops and nose piece. Three (3) ply, splash resistant,

Box of 50pcs

Synonym: Procedure /face masks / medical mask

Intended Use

Medical mask is intended to be worn by medical personnel during surgical or other medical procedures to protect both the patient and the operating personnel from transfer of microorganisms, body fluid and particulate material transfer. It can be also worn for protection against viruses and bacteria propagation in droplets of human body - for regular citizens.

Reduces exposure to blood and body fluids in droplets. Minimizes patient contamination to exhaled microorganisms. This product is intended for use in infection control practices.

Technical Specifications

TYPE I

Mask construction includes:

1. Main part made of nonwoven and melt blown fabrics.

1.1 Spunbound nonwoven polypropylene 20g-35g/m² for inner and outer layers of mask.

1.2 Melt blown polypropylene BFE95 20-35g/m² for middle, filtration layer of mask.

One of the conditions must be fulfilled:

>95% Bacterial Filtration Efficiency (BFE) at 5 micron capacity;

or

>90% Bacteria Filtration Efficiency (BFE) at 3 micron capacity.

Condition varies according to exact Laboratory test method.

TYPE II

Mask construction includes:

1. Main part made of nonwoven and melt blown fabrics.

1.1 Spunbound nonwoven polypropylene 20g-35g/m² for inner and outer layers of mask.

1.2 Melt blown polypropylene BFE99 20-35g/m² for middle, filtration layer of mask.

One of the conditions must be fulfilled:

>99% Bacterial Filtration Efficiency (BFE) at 5 micron capacity;

or

>95% Bacteria Filtration Efficiency (BFE) at 3 micron capacity.

Condition varies according to exact Laboratory test method.

1.3 Main part size: 175 x 95mm. Three Ply construction sealed with ultrasonic pressing machine. 3 pleats of folds to allow the user to expand the mask so it covers the area from the nose to the chin.

1.4 Color: Blue, White, Green, Purple

2. Nose bridge for possibility to shape by hand upper edge, to follow nose shape and make mask more airtight. Made of plastic and soft wire.

3. Ear loops welded to main part with ultrasonic welder, made of latex free rubber with plaited shield.

Usage: For Single use only.

CE marked.

Primary packaging: Unit of use (1) box of 50 masks

Secondary packaging: 24 cases of 50 masks /box (1200 pieces/case)

Labelling on the primary packaging:



Manufacturer:



Verdent sp. z o.o.
ul. Częstochowska 38/52
93-121 Łódź
Poland
NIP: 728-279-03-98

For Polish inquiries :

+48 42 207 10 51

For International inquiries:

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+ 48 42 207 10 53

+ 48 42 207 10 54

www.verdent.pl



Complies with PN-EN 14683+AC:2019-09



2025-04-01

EN Medical, disposable face mask

3-layers, with earloops, type II, single use

Instruction:

Grab the rubber bands with your hands and attach to your ears to cover your mouth and nose.

Shape the upper edge of the mask to allow it to follow nose shape.

After use, remove by touching only earloops, throw away and wash your hands thoroughly.

PL Maska medyczna

3-warstwowa, z gumkami, typ II, jednorazowego użytku

Instrukcja:

Chwyć dłońmi za gumki i załóż na uszy, upewnij się, że maska zasłania usta i nos.

Uformuj górną krawędź maski, aby ściśle przylegała do skóry.

Po użyciu zdejmij, dotykając wyłącznie gumek zauszniaków, wyrzuć i umyj starannie ręce.



PL Maska medyczna, jednorazowego użytku, z gumkami

EN Medical mask, disposable, with earloops

DE Einweg-Schutzmaske, mit Gummi

FR Masque médical, jetable, avec élastiques

RU медицинская маска, одноразовая, на резинках

ES Mascarilla médica, desechable, con gomas

IT Mascherina medica, monouso, con elastici

AR قناع طبي قابل التخلص، مطاط على الأذنين

Jacek Karolczak R&D Dept.

Analytical Report Nr.

AR-20-YL-004186-01

Sample code Nr.

560-2020-00004612

Date

21/07/2020

ANALYTICAL REPORT**Client Information**

Eurofins Polska Sp. z o.o.
ul. Księcia Ziemowita 53 blok 3A lok. 4
WARSZAWA POLONIA

justynanowak@eurofins.com

For the attention of Justyna Nowak

Sample Information

Order Code: EUAA70-00007358
Reception Date: 15-Jul-2020
Analysis Starting Date: 15-Jul-2020
Analysis Ending Date: 21-Jul-2020
Sample described as: Masks

Information provided by the customer:

Client Reference: 122-2020-00073105
Sample Description:
Customer requirements: No requirements / Sin Requisitos
Purchase Order Number:

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SAMPLE PICTURE



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CONCLUSION:

TEST PROPERTY	PASS	FAIL	REMARKS
Splash resistance pressure ISO 22609:2004			
A - Mask			REFER RESULT

Remark: Test has been performed as per application request

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COMPONENT LIST:

COMPONENT ID	COMPONENT NAME	MATERIAL DESCRIPTION	COLOR	REMARKS
CUST 01	A - Mask	Mask	Blue	---

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MASKS TESTING

CAS No.

RESULTS

UNC.

LOQ

GUIDELINES

Analyses on:A - Mask◆ **Splash resistance pressure**

Analysis Ending Date: 21/07/2020

ISO 22609:2004

Splash resistance pressure

16 kPa

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Complete test data reported at Annex.

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Signed for and on behalf of Eurofins Textile Testing Spain:

Eurofins Textile Testing Spain, S.L.U.
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03007 Elche (Alicante)
B-978099

Report electronically validated by

Maria Jesus Martinez Puig

Chemical Lab manager

EXPLANATORY NOTE

- ◆ Test not covered by ENAC accreditation scope
- Test is subcontracted within Eurofins group and is accredited
- Test is subcontracted within Eurofins group and is not accredited
- Test is subcontracted outside Eurofins group and is accredited
- Test is subcontracted outside Eurofins group and is not accredited

N/A = Not Applicable

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End Of Report

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DETERMINATION OF PRESSURE OF SPLASH RESISTANCE

Test Method: ISO 22609:2004

Number of test specimens: 32

Sample size: Circular, diameter 5,58 cm

Sample area tested: 24,5 cm²

Pressure: 16 kPa (120,0 mm Hg)

Conditioning: 23 °C; 85 % Hr

Enviornmental test conditions 24 °C; 82 % Hr

Specimen	Results	
	Pass	Fail
1	X	
2	X	
3	X	
4	X	
5	X	
6	X	
7	X	
8	X	
9	X	
10	X	
11	X	
12		X
13	X	
14	X	
15	X	
16		X
17	X	
18	X	
19	X	
20	X	
21	X	
22	X	
23	X	
24	X	
25	X	
26	X	
27		X
28	X	
29	X	
30	X	
31	X	
32	X	

Observation:

An acceptable quality limit of 4% is met for a single sampling when 29 or more of the 32 tested specimens show "pass" results.

Conclusion	PASS
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Operating requirements for surgical masks based on EN 14683: 2019+AC: 2019 standard

TEST	TYPE I	TYPE II	TYPE IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm ²)	< 40	< 40	< 60
Splash resistance pressure (kPa)	Not required	Not required	≥ 16
Microbial cleanliness (CFU/g)	≤ 30	≤ 30	≤ 30