

NUNDINAE GROUP D.O.O.

VOJKOVO NAČRTEŽJE 23

6000 KOPER-CAPODISTRIA, SLOVENIA-EU

VAT NO.: SI55756018

EMAIL: team@nundinae-group.com

PHONE: +386 41 99 77 73

SITE: [HTTPS://NUNDINAE-GROUP.COM](https://nundinae-group.com)



3-PLY IIR SURGICAL MASK

MUMU

Country of Origin: Turkey

Product Imported by: Nundinae Group d.o.o.

PRODUCT SPECIFICATION:

Type: Surgical Mask, 3-ply with earloop

Material: Polypropylene non-woven fabric (25 GSM), latex-free. Endless filaments spunbound, thermally bonded.

Color: Blue/Light blue

Design and features: 3-ply structure

Storage: Allows for properties maintenance when stored in dry conditions. Do not expose product to direct sunlight.

Shelf-life: 5 years from the date of manufacturing

REGULATION AND QUALITY STANDARD REFERENCE:

Manufactured under: EN ISO 13485:2016 and EN ISO

9001:2015+AC Quality Management System

Standard conformity: EN ISO 15223-1; MDD 93/42/EEC; EN ISO 1041; EN ISO 14683:2019+AC:2019; EN ISO 62366-1; EN ISO 14971

SIZE:

Uniform size.

FUNCTIONALITY AND SUGGESTED USE:

- Breathable, non-irritating fabric
- Protection from bacteria, microorganisms and other liquid parts, bodily fluids, and particles
- Adjustable and flexible, so it can fit according to each face measures and shapes.
- Suitable for use in the medical sector – hospital and laboratory environment. Intended for medical use for cross-contamination protection/infection control practices.

CONFECTION AND PACKAGING:

Primary confection:

Box of 50 masks. Product specification and properties marked on packaging.

Secondary confection:

Carton of 60 boxes or 3.000 masks.



TECHNICAL FILE

MUMU SURGICAL MASKS

Rev-August



MY TİCARET VE MEDİKAL A.Ş.
Ömerli Mahallesi General Şükrü Koralı Caddesi No:33 Arnavutköy
İstanbul/TURKEY
www.mymedikal.com.tr info@tmytmedikal.com.tr

0. DEFINITION :

Mumu 3-ply surgical mask (facial mask for medical use), can be fit according to each face measures and shapes, flexible and can be used without disturbing the soft structure. Air permeable and lets breathing easily. Non-irritating. Provides protection against bacteria.

1. QUALITY SYSTEM OF MY TICARET VE MEDİKAL :

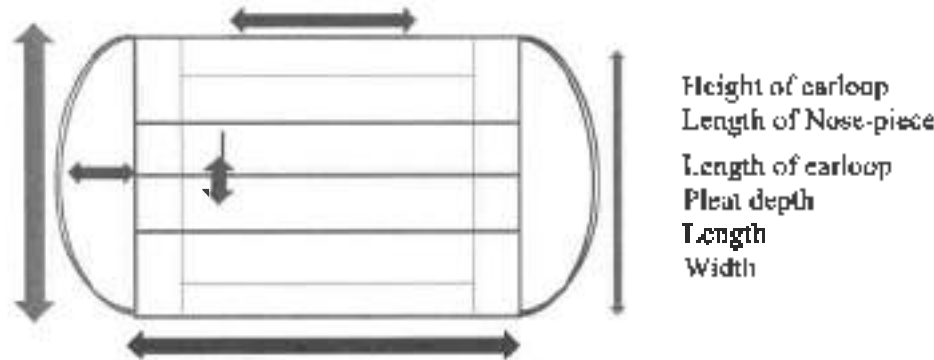
MY TICARET VE MEDİKAL has been manufacturing its products with the quality systems as given below;

- EN ISO 13485:2016 Quality Assurance System-Medical Devices
- EN ISO 9001:2015-AC Quality Assurance System

2. PRODUCT IDENTIFICATION AND RECOMMENDED USE :

The product is made by non woven fabric. The product's composition is polypropylene and does not includes latex. The product is breathable and has no special personal on environmental hazards. The product is made automatically in hygienic conditions. The product prevents the potential reactions between all kind of liquids and particles, microorganisms.

Ref No:	MM.NS.LM.01
Ref No:	MM.NS.LM.29



Dimension (With ear loop)	Body Size	Length	175 mm(+/-10mm)
		Width	95 mm(+/-10mm)
	Height of Earloop		70 mm
	Length of Earloop		160 mm(+/-10mm)
	Pleat Depth		10 mm
	Length of Nose-piece		90 mm (+/-10mm)

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Ömerli Mah. General Şükrü Koralın Cad. No:33 Arnavutköy, İstanbul/TURKEY

Pbx: +90 212 438 20 64 Fax: +90 212 438 20 65 www.mymedikal.com.tr info@mymedikal.com.tr

TECHNICAL FILE
Mumu 3-Ply Surgical Masks
(Facial Mask for Medical Use)

Dimension (Infant)	Body Size	Length	145 mm(+/-10mm)
		Width	95 mm(+/-10mm)
	Height of Earloop		70 mm
	Length of Earloop		160 mm(+/-10mm)
	Pleat Depth		10 mm
	Length of Nose-piece		70 mm (+/-10mm)

Dimension (With Ties)	Body Size	Length	175 mm(+/-10mm)
		Width	95 mm(+/-10mm)
	Length of Tie		40 mm(+/-5mm)
	Pleat Depth		10 mm
	Length of Nose-piece		90 mm(+/-10mm)

3. SUBSTANCE/MIXTURE OF RAW MATERIAL :

Characteristic	Specification		
Materials	Mask Body	Outer Material	Spunbond 25 gr (+/-5gr)
		Filter Layer	Meltblown 25 gr (+/-5gr)
		Inner Material	Spunbond 25 gr (+/-5gr)
		Ear loop	Lycra-Elastane
		Tie	Spunbond 40 gr (+/-5gr)
		Nose-piece	Aluminium wire

3.1. Material Safety Data Sheet (MSDS)

3.1.1. Composition:

Identification of the type of nonwoven product.

Thermobonded Nonwoven by calendering

process

Polypropylene CAS No: 25085-53-4 spunbond-meltblown modification

Web surface treatment - Concentration above 1st/0.....*No.

Binder.....*No

Additives.....*Yes.

May contain color pigments if the product is in color. White color may contain

TiO₂. Other major components.....*No

Chemicals (in relevant concentration) that are in list of dangerous substances...*No

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3.1.2. Hazards identification

Under normal conditions of use and handling, this product is not expected to create any health or safety hazards.

Accidental thermal decomposition or melting state can present hazards.

3.1.3. First-aid measures

Under normal condition ;

Inhalation.....	No specific measure to be taken
Skin contact.....	No specific measure to be taken
Eyes contact.....	No specific measure to be taken
Ingestion.....	No specific measure to be taken

3.1.4. Fire fighting measures

1. Suitable extinguishing media;

Water spray, dry chemical or CO2 extinguisher. No special procedures are expected to be necessary for this product. Normal fire fighting procedures should be followed to avoid inhalation of smoke and gases

2. Extinguishing media not to be used None

3. Special exposure hazards For flammable and toxic fumes as well as skin contact with molten materials see § 10

4. Special protective clothing for fire-fighter..... None. It is recommended that fire-fighters should wear full protective clothing including self contained breathing apparatus.

3.1.5. Accidental release measures

Personal Precautions: Avoid dust formation. Forms slippery surface.

3.1.6. Handling and storage

Keep in a dry and closed area with the original packing. The packages have to be handled so that they can not break and to be arranged as to prevent them from falling. The goods shall be handled with good industrial hygiene and safety practice.

3.1.7. Exposure controls / personal protection

No specific measures. Handle in accordance with good industrial hygiene and safety practice. Use of safety glasses and face mask is recommended if dust is formed during application.

3.1.8. Physical and chemical properties

Aspect.....	Solid, in rolls or sheets
Appearance (the colour of the product as supplied).....	Normally white if not a specific color is mentioned.
Odour.....	Practically odorless
Ph.....	Not applicable

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Boiling point/boiling range	Not applicable
Melting point/melting range	(Polypropylene 165°C (330°F))
Decomposition temperature	> 260°C (500°F)
Flash point	Not applicable
Flammability	Not easily flammable
Explosive properties	Not applicable
Oxidizing properties	Not applicable
Vapour pressure	Not applicable
Static electricity	The product can develop and/or
accumulate static electricity, (i.e. by rubbing or friction)	
Solubility	Water insoluble - fat
insoluble	
Partition coefficient	Not applicable

3.1.9. Stability and reactivity

The product is stable at room temperatures and does not decompose or self react when handled and stored under prescribed conditions. Toxic fumes can be generated under thermal decomposition.

3.1.10. Toxicological information

No toxic reaction known under normal conditions. Particularly, no case of coetaneous sensitisation or of mutagenic / carcinogenic activity is known. Under decomposition conditions, toxic fumes and contaminated water.

3.1.11. Ecological information

For transportation, storage and normal use no toxicological effect known. The fabric will not degrade biologically in short term.

3.1.12. Disposal considerations

As non hazardous solid waste, depending on local registration, nonwovens can be disposed of through recycling, landfill.

3.1.13. Transport information

Not classified as dangerous for transport.

3.1.14. Regulatory information

Not classified as dangerous in compliance with Turkey and European regulation regarding classifying, packaging and labeling of hazardous substances and products.

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TECHNICAL FILE
Mumu 3-Ply Surgical Masks
(Facial Mask for Medical Use)

3.2. Technical Data Sheet and Certificate

TECHNICAL DATA SHEET			
Product :		Polypropylene	
Product Description :		NONWOVEN 3-PLY, THERMALLY BONDING	
Face Material :		100% PP	
Appearance of Fabric :		IS HYDROPHOBIC	
Thickness :			
Fabric Colour :		WHITE	
Customer Name :			
Weight :		25 GRS	
Width :			
Packing :		75 BAG WITH LABEL	
PROPERTIES	TEST METHOD	UNIT	TARGET
WEIGHT	ANISO 130.1.03 (15)	g/m ²	25
THICKNESS	ANISO 120.1.03 (14)	mm	0.25
TENSILE STRENGTH	ANISO 110.1.03 (13)	N/5 cm	55.5
			24.5
ELONGATION AT BREAK	ANISO 110.1.03 (13)	%	126.8
			134.3
Tolerances For The Average Results			
Weight	± 5%	Test Tolerances Length : - 0 - +3% against target / ordered length Width : Up to 150 cm in width - 0cm +3cm Over 150 cm in width - 0cm +20 Splice : 10% against target in per mill	
Thickness	± 10 %		
Tensile Strength	± 15 %		
Elongation	± 15 %		
Hydrostatic Head	± 15 %		
Liquid Strike-Through Time	± 10 %		
Air Permeability	± 20 %		
Absorption	± 20 %		
The product is stored under clean, dry and free from moisture in polyethylene film. The code label, with product code, description and lot details are applied to the contents of each pack and a small label is applied to each roll. Packaging should only open by following and the patient used clean wrapped.			
Preparation Date	QUALITY CONTROL APPROVAL		
01.04.2020			

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CERTIFICATE

The company

BAYTEKS TEKNIK TEKSTİL SAN. VE TİC. A.Ş.
Organize Sanayi Bölgesi 19 Nolu Cadde No. 9
79000 Merkez - Kilis, TURKEY

is granted authorisation according to STANDARD 100 by OEKO-TEX® to use the STANDARD 100 by OEKO-TEX® mark, based on our test report **21.0.46640**

OEKO-TEX®
CONFIDENCE IN TEXTILES
STANDARD 100
06.MQ.41419 HOHENSTEIN HTTI



Tested for harmful substances
www.oeko-tex.com/standard100



for the following articles:

Nonwoven spunbonded, melt blown and their composite structures produced from white and masterbatch (pigment dyestuff) dyed polypropylene and polypropylene/polyethylene (reprocessing of own material), with and without PE lamination (in colour blue) and additives including UV stabiliser.

The results of the inspection made according to STANDARD 100 by OEKO-TEX®, Annex 4, **product class II** have shown that the above mentioned goods meet the human-ecological requirements of the STANDARD 100 by OEKO-TEX® presently established in Annex 4 for products with direct contact to skin.

The certified articles fulfil requirements of Annex XVII of REACH (incl. the use of azo colourants, nickel release, etc.), the American requirement regarding total content of lead in children's articles (CPSIA; with the exception of accessories made from glass) and of the Chinese standard GB 18401:2010 (labelling requirements were not verified).

The holder of the certificate, who has issued a conformity declaration according to ISO 17050-1, is under an obligation to use the STANDARD 100 by OEKO-TEX® mark only in conjunction with products that conform with the sample initially tested. The conformity is verified by audits.

The certificate 06.MQ.41419 is valid until 31.03.2022

Bönnigheim, 20.04.2021


Dipl.-Ing. (FH) Ivonne Schramm
Head of Certification Body OEKO-TEX®



TECHNICAL FILE
Mumu 3-Ply Surgical Masks
(Facial Mask for Medical Use)

4. PERFORMANCE REQUIREMENTS OF FINISHED PRODUCTS

We declare our products comply with EN 14683:2019+AC:2019 as TYPE IIR and that all test results are the same for all the products (infant/adult/earloop/tie). Because all of the products are made from the same raw materials.

Parameters	Units	Method	Results	Test Results
BFE (Filtration)	%	EN 14683:2019+AC:2019	≥98	% 98,4 (Ekoteks-20031582)
Differential pressure (Breathability)	Pa/cm ²	EN 14683:2019+AC	<40	24,7 (Ekoteks-20031582)
Microbial cleanliness / bioburden (this is also requested in Portugal now)	cfu/g	ISO 11737-1:2018	≤30	16 (Ekoteks-20031582)
Splash resistance pressure	kPa	ISO 22609	≥16	21,3 (Ekoteks-20031582)
Bioincompatibility		ISO 10993-1	Suitable for Skin Irritation, Cytotoxicity, Sensitization	Cytotoxicity: It is not cytotoxicity. (Oxygen-2020-C-1099) Irritation: The sample has passed the irritation test. (Kocaeli University-2020-32) Sensitization: The sample has passed the sensitization test. (Kocaeli University-2020-33)

5. INSTRUCTIONS FOR

USE 5.1.Intended Use:

Surgical mask (facial mask for medical use) is intended to be worn by medical personnel during surgical or other medical procedures to protect both the patient and the operating personnel and any other person that want and need to be protected, from transfer of microorganisms, body fluid, particulate material transfer and any other microbes.

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

5.2. Technical Specifications:

Non-irritating, Fluid Resistant, Three Ply construction.3 pleats of folds to allow the user to expand the

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TECHNICAL FILE
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(Facial Mask for Medical Use)

mask so it covers the area from the nose to the chin. Mask is secured with an ear loop to be placed behind the ears.

The surgical mask's (facial mask for medical use) three-ply layers work as follows:

- **The outer layer** repels water, blood, and other body fluids.
- **The middle layer** filters certain pathogens.
- **The inner layer** absorbs moisture and sweat from exhaled air.

5.3. Donning The Mask:

- Before putting on the mask, wash your hands for at least 20 seconds with soap and water, or rub your hands together thoroughly with alcohol-based hand sanitizer.
- Check for defects in the face mask, such as tears or broken loops.
- Position the colored side of the mask outward.
- If present, make sure the metallic strip is at the top of the mask and positioned against the bridge of your nose.
- Ear loops: Hold the mask by both ear loops and place one loop over each ear.
- Mold the bendable metallic upper strip to the shape of your nose by pinching and pressing down on it with your fingers.
- Pull the bottom of the mask over your mouth and chin.
- Be sure the mask fits snugly.
- Don't touch the mask once in position.
- If the mask gets soiled or damp, replace it with a new one.

!! Do not:

- touch the mask once it's secured on your face, as it might have pathogens on it
- dangle the mask from one ear
- hang the mask around your neck
- reuse single-use masks.

If you have to touch the face mask while you're wearing it, wash your hands first. Be sure to also wash your hands afterward, or use hand sanitizer.

5.4. Doffing The Mask:

- Before you take off the mask, wash your hands well or use hand sanitizer.
- Avoid touching the mask itself, as it could be contaminated. Hold it by the loops, ties, or bands only.
- Carefully remove the mask from your face once you: unhook both ear loops.
- Holding the mask loops discard the mask by placing it in a covered trash bin.
- After removing the mask, wash your hands thoroughly or use hand sanitizer.

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TECHNICAL FILE
Mumu 3-Ply Surgical Masks
(Facial Mask for Medical Use)

6. FIRE FIGHTING MEASURES :

Suitable Fire Extinguishers and Methods:

Water spray, foam, carbon dioxide or dry chemicals. A sudden intervention should be made to the fire exit without any possible danger. If the material is melted, do not apply direct water flow. Use fine water spray or foam.

7. DISPOSAL CONSIDERATIONS :

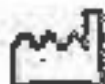
Dispose of according to the Regulation on Control of Hazardous Wastes.

8. USE AREAS :

Hospitals, medical companies, doctor offices, laboratories, food manufacturers, cleaning companies and work places where the hygienic areas are necessary.

9. SHELF LIFE : 5 Years

10. SYMBOLS :

	Production Date		Shows the conformity to the European standards for the self-declared Class I products
	Manufacturer		Keep Dry
	Expiration Date		Keep out of sunlight
	Lot Number		Non-Sterile
	Reference Number		Do not use again

11. STORAGE :

Capable of being stored continuously in ambient temperature of 10 to 30 deg C and relative humidity of 15 to 55%. Capable of operating continuously in ambient temperature of 10 to 30 deg C and relative humidity of 15 to 55%.

It is recommended that surgical face masks (facial mask for medical use) should be stored in their original containers and should be stored away from direct sunlight, heat sources and liquids, including chemicals. The area should be clean and should protect the masks from contamination. Never store it in a purse or pocket.

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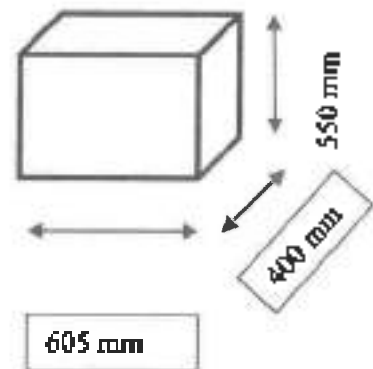
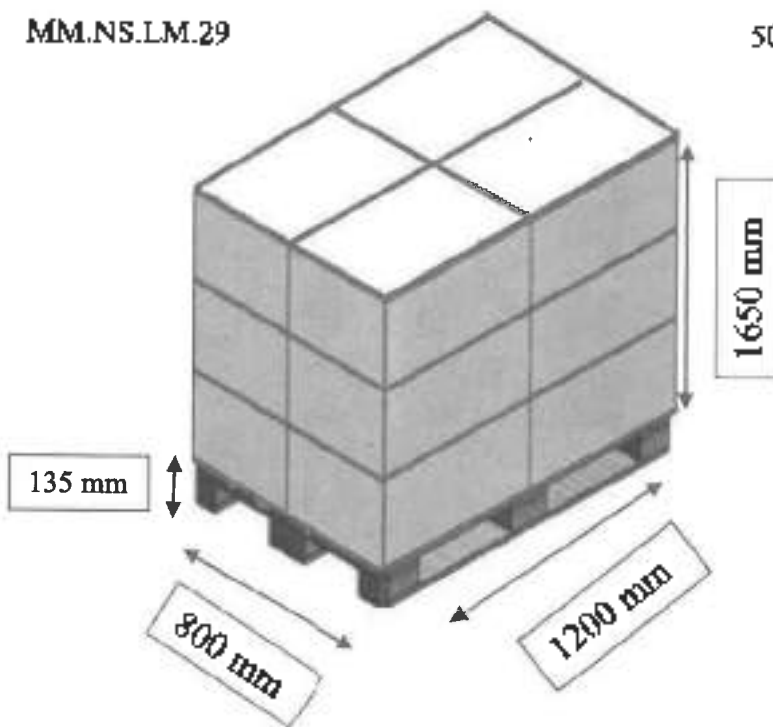
Pbx: +90 212 438 20 64 Fax: +90 212 438 20 65 www.mymedikal.com.tr info@mymedikal.com.tr

12. SAFETY INFORMATION

- Pay attention to the warnings.
- It is not sterile.
- It is for single use only.
- Do not use if the package is damaged.
- Do not use the product after expiration date.

13. PACKAGING

<u>Ref. No.</u>	<u>Quantity per Box</u>
MM.NS.LM.01	50 pcs
MM.NS.LM.29	50 pcs



Quality Assurance Manager
Vedat ÇETİN

MEDICAL AND PHARMACEUTICAL
 1000 N. 10th St., Suite 100, Phoenix, AZ 85004
 Tel: (602) 254-4444 Fax: (602) 254-4445

Hohenstein Istanbul Tekstil Analiz ve Kontrol Hizmetleri Ltd. Sti. - Cumhuriyet Mah. 1990. Sok. No: 8, Çınarpark Residence, A Blok, Dükkan: 5 - 34515 Esenyurt - İstanbul Turkey
BAYTEKS TEKNİK TEKSTİL ŞAN. VE TİC. A.Ş.
 Organize Sanayi Bölgesi 19 Nolu Cadde No: 9
 79000 MERKEZ - KİLİS
 TURKEY

Hohenstein İstanbul Tekstil Analiz ve Kontrol Hizmetleri Ltd. Sti.
 Cumhuriyet Mah. 1990. Sok. No: 8,
 Çınarpark Residence, A Blok, Dükkan: 5
 34515 Esenyurt - İstanbul
 Turkey

OEKO-TEX® Department
 Phone: +90 212 867 2400
 Fax: +90 212 867 2425
 E-Mail: s.bicak@hohenstein.com.tr

Business process	Contact person	Our Ref.	Date
21.1003954	Bicak, Evrim	EBI	16. March 2021

STANDARD 100 by OEKO-TEX® - Confirmation of order receipt

Thank you very much for your order! We are pleased to confirm the following details:

Test no:	21.D.46640
Certificate no:	06.MO.41419
Contact person:	Kadir Karagün Phone: +90 3483 373030 Fax: +90 342 337 2136 E-Mail: kadir.karagun@bayteks.com
Date of order:	1/15/2021
Details of order:	Certification of textile products with the label „Confidence in Textiles - Tested for harmful substances according to STANDARD 100 by OEKO-TEX® Annex 4“
Test material:	Nonwoven spunbonded, melt blown and their composite structures produced from white and masterbatch (pigment dyestuff) dyed polypropylene and polypropylene/polyethylene (reprocessing of own waste), with and without PE lamination (in colour blue) and additives including UV stabiliser.
Product class:	II

Herewith we confirm that you have applied for STANDARD 100 by OEKO-TEX®. If all criteria meet the requirements of the standard you will get the certificate.

This confirmation must not be treated equivalent to an Oeko-Tex® certificate! It does not entitle to mark articles with the Oeko-Tex® label or to make advertising with the Oeko-Tex® label before having a valid certificate.

It has to be emphasized that any kind of incorrect use of the Oeko-Tex® label will cause legal steps.

This confirmation is valid until 16. June 2021.

Best regards,

Hohenstein İstanbul Tekstil Analiz ve Kontrol Hizmetleri Ltd. Stl.

(This is a computer generated document and it is legally binding without signature)



Original Equipment Manufacturer Statement

MY TİCARET VE MEDİKAL A.Ş. We declare that, on behalf of MGI GRUP İTH. İHR. VE DIŞ TİC. LTD. ŞTİ., pieces are produced in the form of the information below. All responsibility for the production belongs to MY TİCARET VE MEDİKAL A.Ş.

Barcode: 8682279944067

Lot: SD20200310

Ref. No: MM.N5.LM.01

Product and Expiry Date: 10.03.2020 - 10.03.2025

Date: 08.07.2020

Name-Surname: MURAT YILDIZ

Title: CEO

Sign :

MY TİCARET VE
MEDİKAL ANONİM ŞİRKETİ
Ömerli Mah. General Şükrü Koralı Cad.
No: 33 Arnavutköy / İSTANBUL
Boydere Mah. No: 125 040 4605
Tel: 0 (212) 438 20 64 Fax: 0 (212) 438 20 65
www.mymedikal.com.tr

MY TİCARET VE MEDİKAL A.Ş

Ömerli Mah. General Şükrü Koralı Cad. No:33 Arnavutköy / İstanbul / TURKEY

Tel: 0 (212) 438 20 64 Fax: 0 (212) 438 20 65

info@mymedikal.com.tr www.mymedikal.com.tr



EC DECLARATION OF CONFORMITY

- Manufacturer's Name:** *MY TİCARET VE MEDİKAL A.Ş.*
- Manufacturer Address:** *Ömerli Mah. General Şükrü Koralı Cad. No:33
Arnavutköy/İSTANBUL*
- Medical Devices:** *Surgical Mask, 3-ply with earloop
Ref No: MM.NS.LM.01*
- Classification:** *Medical Device Directive-Annex IX, Rule I, Class-I (Type IIR)*
- GMDN Code and Term:** *57794 / Surgical – Medical Respirator*
- Scope of Application:** *All batches supplied to which the Declaration of Conformity
Procedure has been applied.*
- Declaration:** *Conformity of the products has been assessed in accordance
with Annex VII of the Directive. A dossier of technical
documentation, as required by the Directive is available. The
product listed is designed, manufactured and tested in
accordance with the information set out in the dossier. We
declare our products comply with EN 14683:2019+AC:2019 as
Type IIR*
- Verification Certificates:** *Quality Management System- Medical devices
EN ISO13485:2016 Certificate No: ISO 02 836 1179
Quality Management System
EN ISO 9001:2015 Certificate No: ISO 01 940 117*

Standards Applied:

<i>EN ISO 13485</i>	<i>Medical devices-Quality management systems - Requirements for regulatory purposes</i>
<i>EN ISO 9001:2015</i>	<i>Quality management systems</i>
<i>EN ISO 15223-1</i>	<i>Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied</i>
<i>MDD 93/42/EEC</i>	<i>Medical devices directive</i>
<i>EN ISO 1041</i>	<i>Information supplied by the manufacturer of medical devices</i>
<i>EN ISO 14683:2019+AC: 2019</i>	<i>Medical face masks - Requirements and test methods</i>
<i>EN ISO 62366-1</i>	<i>Medical devices - Part 1: Application of usability engineering to medical devices</i>
<i>EN ISO 14971</i>	<i>Medical devices - Application of risk management to medical devices</i>

Authorized Signatory**Name-Surname :** Murat YILDIZ**Position :** CEO**Signed :**

İSİY TİCARET VE
MEDİKAL ANONİM ŞİRKETİ
Orhan Mah. Gökçe-Şişli Köyü Cad
No: 33 A Blok Kat: 1 İSTANBUL
Büyükdere
Tic. Sic. No: 275464 V.D. 0212 440 4800
Tel: 0212 440 4800 Fax: 0212 438 70 05
www.isiy-medikal.com.tr

Dated : 22.03.2020



Certificate of Registration

This is to certify that
Quality Management System
for Medical Devices
of

MY TİCARET VE MEDİKAL ANONİM ŞİRKETİ

**ÖMERLİ MAHALLESİ GENERAL ŞÜKRÜ KORALTI CAD. NO: 33
ARNAVUTKÖY - İSTANBUL / TÜRKİYE**

complies with requirements of

ISO 13485:2016

This certificate is valid concerning all activities related to:

PRODUCTION AND SALE OF POWDERED/POWDER-FREE LATEX EXAMINATION GLOVES, POWDER-FREE NITRILE EXAMINATION AND PROTECTIVE GLOVES, POWDERED/POWDER-FREE STERILE SURGICAL GLOVES, POWDERED/POWDER-FREE VINYL EXAMINATION GLOVES, SURGICAL MASKS, PROTECTIVE FACE MASK WITH FILTER

PUDRALI/PUDRASIZ LATEKS MUAYENE ELDİVENİ, NİTRİL PUDRASIZ MUAYENE VE KORUYUCU ELDİVEN, PUDRALI VE PUDRASIZ STERİL CERRAHİ ELDİVEN, VİNİL PUDRALI/PUDRASIZ MUAYENE ELDİVENİ, CERRAHİ MASKE, FİLTRELİ KORUYUCU YÜZ MASKESİ ÜRETİMİ VE SATIŞI

ISO 02 836 1179
Certificate No.

Mar. 8, 2021
Date of this Certificate

Feb. 25, 2022
Certification Expiry Date

Feb. 8, 2021
Date of Audit

Feb. 26, 2020
Date of Registration


Managing Director / Director



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Certificate of Registration

This is to certify that
Quality Management System
of

MY TİCARET VE MEDİKAL ANONİM ŞİRKETİ

**ÖMERLİ MAHALLESİ GENERAL ŞÜKRÜ KORALTI CAD. NO: 33
ARNAVUTKÖY - İSTANBUL / TÜRKİYE**

complies with requirements of

ISO 9001:2015

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SPONGE GAUZE COMPRESS, STERIL / NON-STERIL COMPRESSE ABDOMINALE, STERIL / NON-STERILE
COTTON PAD, GAUZE, STERILE / NON-STERILE SURGICAL MASK

LATEKS PUDRALI / PUDRASIZ MUAYENE EL DİVENİ, NİTRİL PUDRASIZ MUAYENE EL DİVENİ, STERİL / NON-
STERİL CERRAHİ EL DİVENİ, STERİL / NON-STERİL SPANÇ GAZ KOMPRES, STERİL / NON-STERİL BATIN
KOMPRES, STERİL / NON-STERİL PAMUKLU PED, GAZLI BEZ,
STERİL / NON-STERİL CERRAHİ MASKE ÜRETİMİ VE SATIŞI

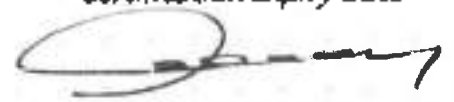
ISO 01 940 1179
Certificate No.

Jun. 5, 2020
Date of this Certificate

Jun. 4, 2021
Certification Expiry Date

May. 28, 2020
Date of Audit

Jun. 5, 2020
Date of Registration


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SENSITIZATION TEST REPORT

ISO-10993-10

JUNE 24, 2020

**KOCAELİ UNIVERSITY UMUTTEPE YERLEŞKESİ
41001 İZMİT/KOCAELİ**



KOCAELİ UNIVERSITY
Experimental Medical Research and Application Unit (DETAB)

Sensitization Test Report
(ISO-10993-10)

Report No.	2020-33
Report Date	24/06/2020
Demand Owner Company/Institution	MY TİCARET VE MEDİKAL A.Ş
Address of Demand Owner Company/Institution	Ömerli Mah. General Şükrü Koralı Cad. No:33 Arnavutköy/ İstanbul Türkiye
Product Name	Surgical Mask
Requested Test	Sensitization Test
Applied Test Standard Reference No.	ISO-10993-10
Applied Test	Guinea Pig Maximization Test
Test Start Date	29/05/2020
Test End Date	23/06/2020

Approved By

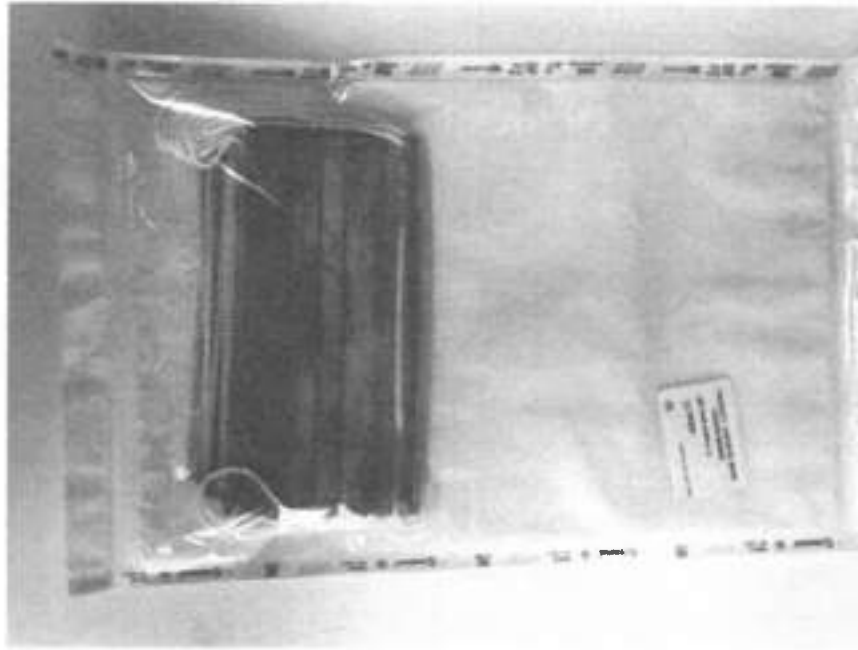
Prof. Dr. Tijen UTKAN

Director of DETAB

Address: Kocaeli University, Umuttepe Yerleşkesi, 41001

A) TEST MATERIAL

Name / Reference and Lot Numbers	Surgical Mask / Lot No: SD20200310
Shipment Type	Cargo
Date of Receipt (dd/mm/yr)	28/05/2020
Production Date (yr)	Not indicated on the package or product
Expiration Date	Not indicated on the package or product
Quantity (Number)	15
Product Description	Blue, 3 layers, with elastic string, non-sterilized filtering mask. All parts were tested.
Description at time of Receipt	Returned to the Owner ☐
	Witness Sample ☒ Archived
	Not received ☐

**Figure 1: Images of the product**

2

Signatures of Researchers in Charge of the Test**Institutional Registry No: 975****Signature****Institutional Registry No: 2021****Signature****Institutional Registry No: 2486****Signature**

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A) Subjects

- Species: Guinea Pig
- Strain: Cavia Porcellus
- Sample Size: Test: 10 and Control: 5
- Age: 4 Months
- Sex: Male
- Housing: Conventional
- Room Temperature: 20-24 °C
- Room Humidity: %30-70
- Room Dark/Light Cycle: 12 hours light/12 hours dark
- Water Consumed (Daily): 100 gr weight/10 ml water
- Feed Consumed (Daily): 100 gr weight/10 g feed
- Feed: Guinea Pig feed
- Weight at the beginning of testing: Table 1

Table 1: Weight 24 hours prior to testing

Test Group		Control Group	
Subject ID	Weight (g)	Subject ID	Weight (g)
1	363	1	307
2	306	2	301
3	301	3	309
4	302	4	309
5	304	5	316
6	301		
7	473		
8	352		
9	341		
10	367		

Signatures of Researchers in Charge of the Test

Institutional Registry No: 975

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B) Sensitization Test (ISO 10993-10)

The sensitization test reported here was applied according to the "ISO 10993 -10:2009 Biological Evaluation of Medical Devices- Part 10: Tests for Irritation and Skin Sensitization, ISO 10993-2:2006 Animal Welfare Requirements and ISO-10993-12:2013 Sample Preparation and Reference Materials" standards.

Aim and Scope: This assay is used for testing the skin sensitization (a delayed hypersensitivity reaction) potential of the material being tested. For this purpose, the guinea pig maximization test method was used. The material was tested on healthy young subjects that weighted at least 300 gr.

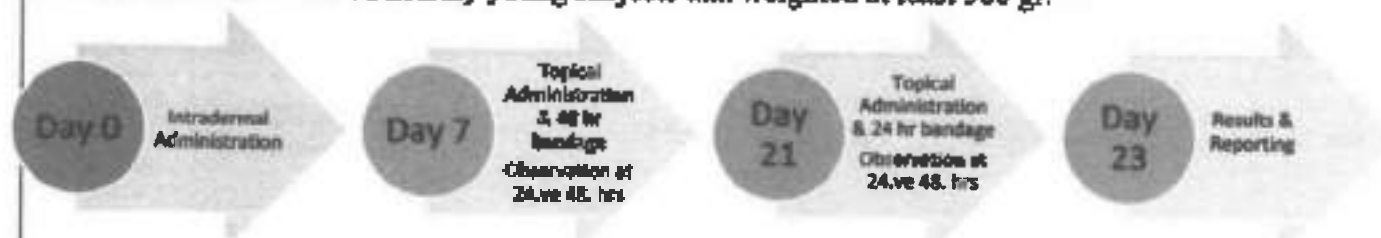


Figure 2: Sensitization Test Plan

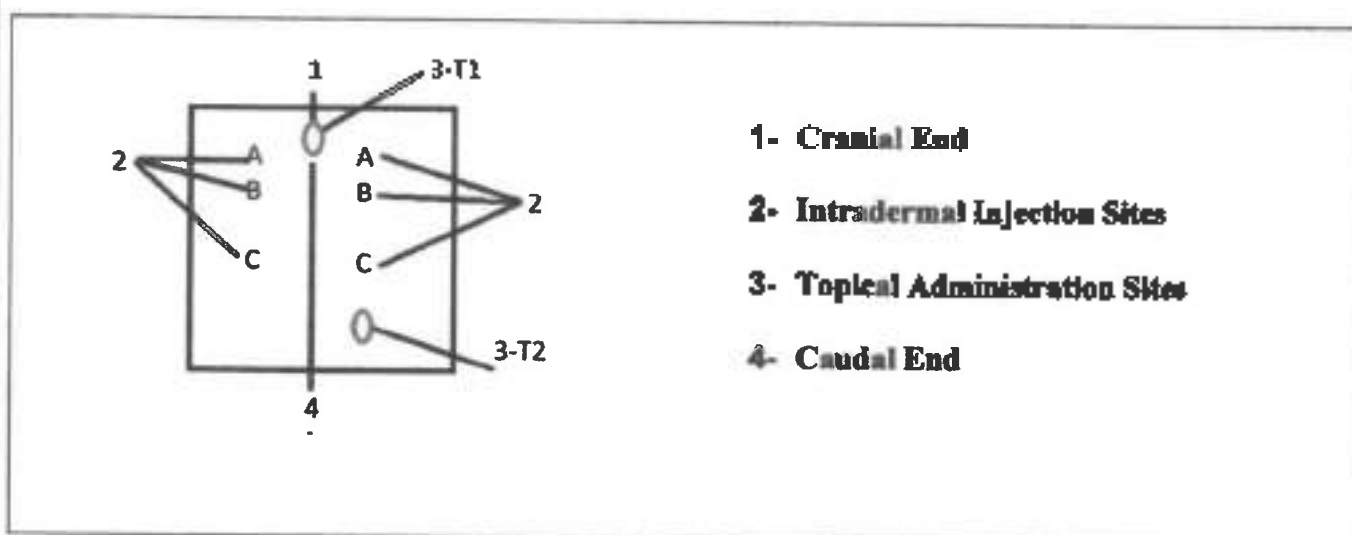


Figure 3: Sequence of administration sites in the Sensitization Test

4

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Preparation of Test Material:

The test material was selected and prepared, and the extracts were prepared in accordance with the ISO 10993-12:2013 standards.

Test Group: For the test administration, extracts were prepared (Table 2).

Control Group: Saline was used as a negative control.

Table 2: Extract Preparation

Material	Sterilization	Amount	Volume	Concentration	Vehicle	Water Temperature	Duration
Folded material with irregular pores	Sterilized in the preparation phase	1 g	10 ml	0.1 g/ml	Saline	72°C	24 saat

Intradermal Injection (Day 0): Intradermal injections (0.1 ml) were administered at sites indicated by 2 on Figure 3 and at ratios as indicated in Table 3.

Table 3: Intradermal Administration

Test group	Control group
a) Freund's Adjuvant Complete (FCA) + Saline solution mixture prepared at 1:1 ratio	a) Freund's Adjuvant Complete (FCA) + Saline solution mixture prepared at 1:1 ratio
b) Test extract	b) Saline
c) Freund's Adjuvant Complete (FCA) + Test extract solution mixture prepared at 1:1 ratio	c) Negative Control + Freund's Adjuvant Complete (FCA) solution mixture prepared at 1:1 ratio

5

Signatures of Researchers in Charge of the Test

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Day 7 Topical Administration (T1) – Topical Induction Phase: 24 hours prior to testing, the test areas on the animals' back were shaved (2 cm x 4 cm; Figure 3). The test extract was administered (0.3 ml) topically at site 3 (Figure 3) close to the cranial end at the interscapular region. The extract at the amount of 0.3 ml was applied on a filter paper (2 cm x 4 cm), which was then bandaged on the test site for 48 hours. 48 hours after the topical administration, the elastic band was removed and the exposed skin was gently washed with warm water. 24 and 48 hours after the bandage was removed, skin sensitization was evaluated according to the Magnusson ve Kligman rating scale (Table 4).

Day 21 Topical Administration (T2) – Challenge Phase: 24 hours prior to testing, the test areas on the animals' back were shaved (2 cm x 4 cm; Figure 3). The test extract was administered (0.3 ml) topically at site 3 (Figure 3) close to the caudal end. The extract at the amount of 0.3 ml was applied on a filter paper (2 cm x 4 cm), which was then bandaged on the test site for 24 hours. 24 hours after the topical administration, the elastic band was removed and the exposed skin was gently washed with warm water. 24 and 48 hours after the bandage was removed, skin sensitization was evaluated according to the Magnusson ve Kligman rating scale (Table 4).

Table 4: Sensitization Scoring

Patch (Filter Paper) Reaction Test	Score
No visible changes	0
Discrete and patchy erythema	1
Moderate and adjacent erythema	2
Severe erythema and swelling	3

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Table 5: Categorization of Guinea Pig Maximization Test Scores

Sensitization ratio %	Category	Class
0	.	Absent
>0-8	I	Weak
9-28	II	Mild
29-64	III	Moderate
65-80	IV	Strong
81-100	V	Extensive
Sensitization Ratio Formula: Positive Score/Total Number of Animals x 100		

D) RESULTS**Table 6: Post-administration Evaluation****1. Scores 7 days after topical administration**

24. hours	1	2	3	4	5	6	7	8	9	10
Test	0	0	0	0	0	0	0	0	0	0
Negative Control	0	0	0	0	0	-	-	-	-	-
48. hours	1	2	3	4	5	6	7	8	9	10
Test	0	0	0	0	0	0	0	0	0	0
Negative Control	0	0	0	0	0	-	-	-	-	-

2. Scores 21 days after topical administration

24. hours	1	2	3	4	5	6	7	8	9	10
Test	0	0	0	0	0	0	0	0	0	0
Negative Control	0	0	0	0	0	-	-	-	-	-
48. hours	1	2	3	4	5	6	7	8	9	10
Test	0	0	0	0	0	0	0	0	0	0
Negative Control	0	0	0	0	0	-	-	-	-	-

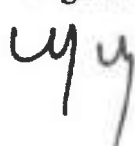
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Signatures of Researchers in Charge of the Test**Institutional Registry No: 975**

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Institutional Registry No: 2021

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Table 7: Evaluation of Test Results

Samples	Sensitization Ratio %
Test Sample	0.00
Negative Control	0.00

E) CONCLUSION AND EVALUATION

According to the test scores (Table 6), the sensitization ratio % of the test sample was 0.00 and the sensitization ratio % of the negative control was 0.00 (Table 7). In conclusion, the test material (MY TİCARET VE MEDİKAL A.Ş, Surgical Mask / Lot No: SD20200310) was categorized as no sensitization (Absent - Table 5) according to the outcomes of the procedures conducted in accordance with ISO 10993-10. **No sensitization of the test sample was detected and the sample has passed the sensitization test.**

B

Signatures of Researchers in Charge of the Test

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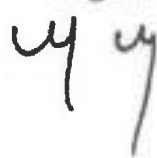
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SKIN IRRITATION TEST REPORT

ISO-10993-10

JUNE 24, 2020

**KOCAELİ UNIVERSITY UMUTTEPE YERLEŞKESİ
41001 İZMİT/KOCAELİ**



KOCAELİ UNIVERSITY
Experimental Medical Research and Application Unit (DETAB)

Skin Irritation Test Report
(ISO-10993-10)

Report No.	2020-32
Report Date	June 24, 2020
Demand Owner Company/Institution	MY TİCARET VE MEDİKAL A.Ş
Address of Demand Owner Company/Institution	Ömerli Mah. General Şükrü Koralı Cad. No:33 Arnavutköy/ İstanbul Türkiye
Product Name	Surgical Mask
Requested Test	Skin Irritation Test
Applied Test Standard Reference No.	ISO-10993-10
Applied Test	Rabbit Skin Irritation Test
Test Start Date	June 11, 2020
Test End Date	June 14, 2020

Approved By

Prof. Dr. Tijen UTKAN

Director of DETAB

Address: Kocaeli University, Umuttepe Yerleşkesi, 41001

A) TEST MATERIAL

Name / Lot Number	Surgical Mask / Lot Number: SD20200310
Shipment Type	Cargo
Date of Receipt (dd/mm/yr)	28/05/2020
Production Date (yr)	Not indicated on the package or product
Expiration Date	Not indicated on the package or product
Quantity (Number)	15
Product Description	Blue, 3 layers, with elastic string, non-sterilized filtering mask. All parts were tested.
Description at time of Receipt	Returned to the Owner ☐
	Witness Sample ☒ Archived
	Not received ☐

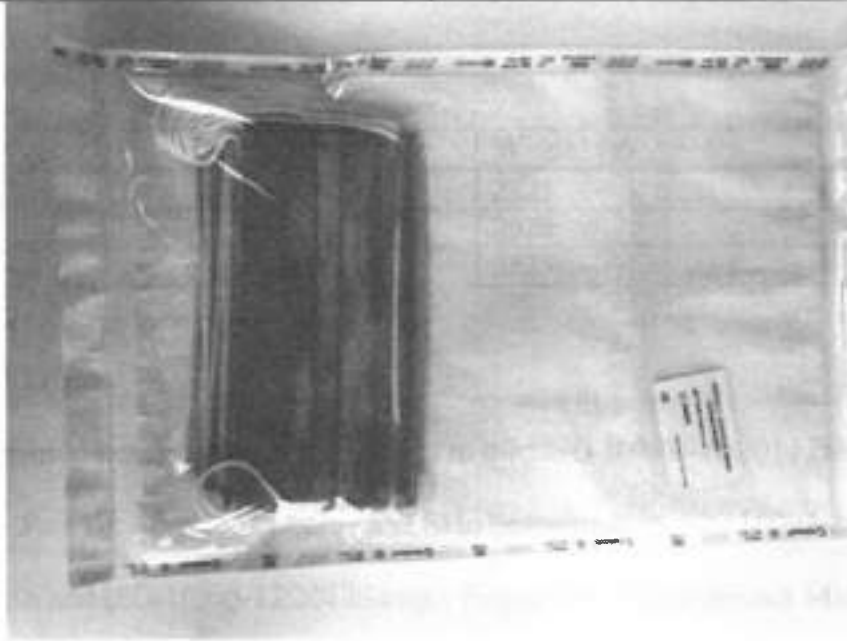


Figure 1: Image of the product

2

Signatures of Researchers in Charge of the Test

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B) Subjects

- Species: Rabbit
- Strain: New Zealand Rabbit
- Sample Size: 3
- Age: 4 Months
- Sex: Female
- Housing: Conventional
- Room Temperature: 20-24 °C
- Room Humidity: %40-60
- Room Dark/Light Cycle: 12 hours light/12 hours dark
- Water Consumed (Daily): 100-600 ml
- Feed Consumed (Daily): 100-300 g
- Feed: MBD rabbit feed
- Weight at the beginning of testing: Table 1

Table 1: Baseline Weights

Subject ID	Weight (g)
1	2825
2	2920
3	2835

C) IRRITATION TEST

The irritation test reported here was applied according to the "ISO 10993-10:2014 Biological Evaluation of Medical Devices- Part 10: Tests for Irritation and Skin Sensitization, ISO 10993-2:2006 Animal Welfare Requirements and ISO-10993-12:2013 Sample Preparation and Reference Materials" standards.

3

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Aim: The rabbit skin irritation test method is used to assess the irritant potential of the test material. The irritation test was conducted with healthy young New Zealand rabbits with a minimum weight of 2 kg. In accordance with the standards indicated in ISO 10993-10, the effects of a four hour-long application on the skin in terms of erythema and swelling was evaluated. The irritation test applications and procedures are illustrated in Figures 2 and 3.



Figure 2: Irritation Test Plan

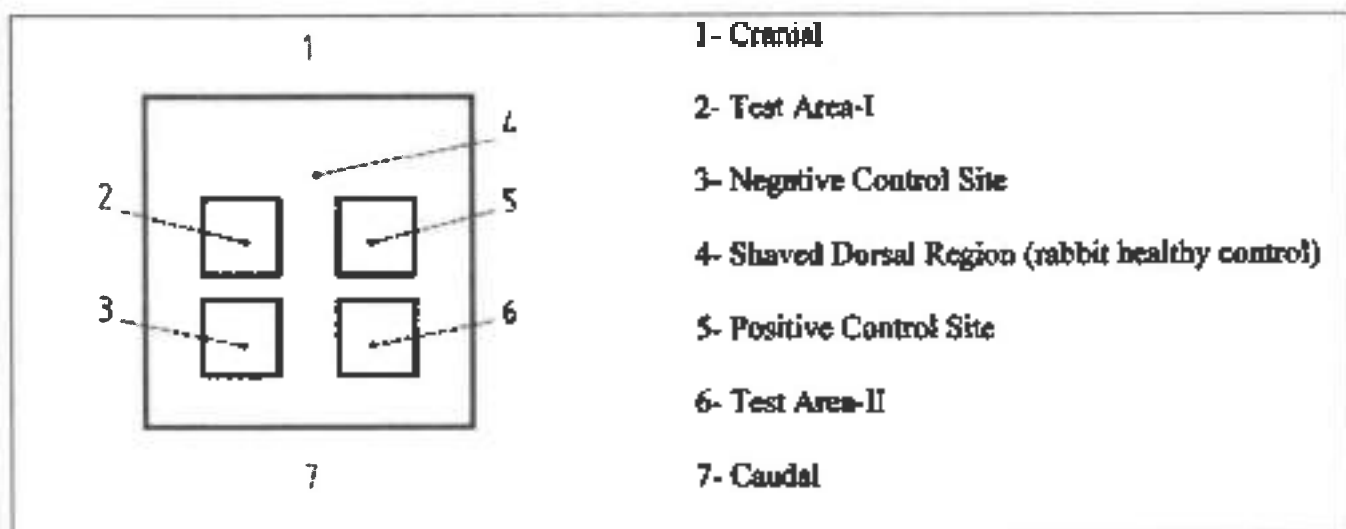


Figure 3: Rabbit Skin Irritation Test Regions

4

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Scope: The test areas of the subjects were shaved (15 cm x 10 cm) 24 hours prior to testing. The materials including extract, negative and positive control solutions were applied at 2 test areas, 1 negative control site and 1 positive control site (Figure 3), respectively. These areas were then bandaged. The bandage was removed 4 hours following the application and the skin was washed gently with warm water. The skin reaction observation and scoring was done after the 1st hour (not considered in evaluation), 24th, 48th, and 72nd hour (Tables 2 and 3).

Table 2: Skin Irritation Scoring

REACTION	IRRITATION SCORE
Erythema and Eschar Formation	
No Erythema	0
Very Slight Erythema (barely perceivable)	1
Well-defined Erythema	2
Moderate Erythema	3
Severe Erythema (beet-redness) and eschar formation	4
Edema Formation	
No Edema	0
Very Slight Edema (barely perceivable)	1
Well-defined Edema (Edges of area well-defined by definite raising)	2
Moderate Edema (raised approximately 1 mm/0.1 cm)	3
Severe Edema (raised more than 1 mm/0.1cm extending beyond exposure area)	4

Table 3: Evaluation categories of primary or cumulative irritation

Average Skin Irritation	Irritation Category
0 – 0.4	Negligible
0.5 – 1.9	Mild
2 – 4.9	Moderate
5 – 8	Severe

Preparation of the test material:

The test material was selected and extract was prepared in according with the ISO 10993-12 standards.

Test Group: Extract was prepared for the topical skin irritation application (Table 4)

Positive Control Group: Sodium Dodecyl Sulfate (SDS, SIGMA L3771) that is known to have an irritant effect was prepared with %5 Saline.

Negative Control Group: USP Reference Standard High Density Polyethylene (lot no:ROM367) that is known not to have an irritant effect was used.

Table 4: Extract Preparation

Material	Sterilization	Amount	Volume	Concentration	Vehicle	Water Temperature	Duration
Folded material with irregular pores	Sterilized in the preparation phase	1 g	10 ml	0.1 g/ml	SF	72° C	24 hours

Application: 0.5 ml test material was applied on each area, which was then covered with a filter paper and bandaged for 4 hours. After this 4 hour-long period, the bandage was removed, the skin was gently washed with warm water and was observed until the end of the evaluation period. In addition, any possible effects on the skin was studied outside the application sites. Detailed observations were made with naked eye and microsurgical microscope (Leica IC90 E). The edema size was measured with a digital caliber.

Signatures of Researchers in Charge of the Test

Institutional Registry No: 975

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Institutional Registry No: 2021

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Institutional Registry No: 2486

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D) RESULTS

Table 5: Evaluation of the skin after the test application

Animal No	Groups	Area*	Observation (hour)							
			Erythema				Edema			
			1. hr	24. hr	48. hr	72. hr	1. hr	24. hr	48. hr	72. hr
1	Test Sample	2	0	0	0	0	0	0	0	0
		6	0	0	0	0	0	0	0	0
	Positive Control	5	0	1	1	1	0	0	0	2
	Negative Control	3	0	0	0	0	0	0	0	0
2	Test Sample	2	0	0	0	0	0	0	0	0
		6	0	0	0	0	0	0	0	0
	Positive Control	5	0	0	1	2	0	0	0	2
	Negative Control	3	0	0	0	0	0	0	0	0
3	Test Sample	2	0	0	0	0	0	0	0	0
		6	0	0	0	0	0	0	0	0
	Positive Control	5	0	1	2	2	0	0	0	2
	Negative Control	3	0	0	0	0	0	0	0	0

Table 6: Average Irritation Test Results

Samples	Irritation Results
Test Sample	0
Positive Control	0.04
Negative Control	0

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Institutional Registry No: 975

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Surgical Mask Lot No: SD20200310

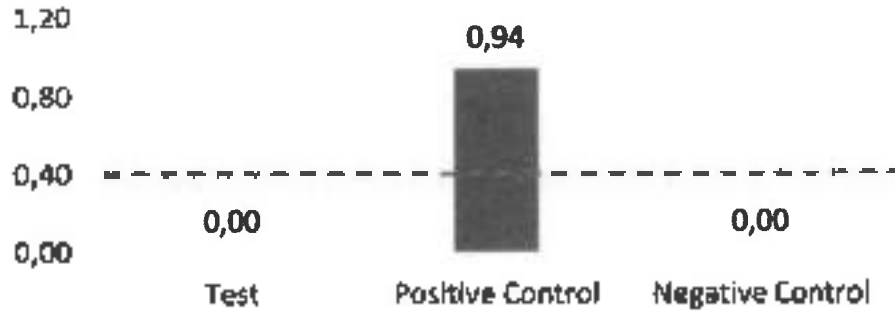


Figure 4: Average of test results

E) CONCLUSION & EVALUATIONS

The skin reactions to the two applications of the extract of the test material as well as one negative control and one positive control application on the back of three New Zealand rabbit were evaluated at three different time points (24., 48., and 72. hours). The results gathered are presented in Figure 4, Tables 5 and 6. According to the average test irritation results, the results for the test sample is 0.00, for the negative control it is 0.00, and for the positive control it is 0.94 (Figure 4; Table 5 and 6). Observations were made also one hour after the four-hour long topical application but they were not included in the results. The scores gathered for the negative control group were evaluated as negligible whereas the scores gathered for the positive control group were evaluated as mild irritant.

In conclusion, based on the results of the irritation tests conducted according to the ISO 10993-10, the test material owned by MY TICARET VE MEDİKAL A.Ş, Surgical Mask, Lot No: SD20200310 was categorized in the negligible group with no erythema or edema (Table 3). No irritant effect of the test sample was detected. The sample has passed the irritation test.

8

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Report Number : 2020-C-1099 Date of Report : 05/06/2020

Purpose of Analysis : Cytotoxicity Test

Customer name/address : MY Ticaret ve Medikal A.Ş. / Çimenli Mah. Genel Sağlık Kurumu Cad. No:33 / İSTANBUL

Name and identity of test item : Surgical Mask

Code of Sample : Lot: SD20200310

Package of Sample/Quantity : 3 piece

Date of receipt of test item : 28/05/2020

Date of Test/End of test : 29/05/2020 - 05/06/2020

Number of pages : 5

Analysis	Unit	Result	Limit of Measurement	Recovery	Uncertainty of Meas.	Analysis Method	Com.
3- rd In Vitro Cytotoxicity Test		In Vitro Cytotoxicity				TS EN ISO 10993-5 (Biological evaluation of medical devices Part 5: Test for in vitro cytotoxicity) TS EN ISO 10993-12 (Biological evaluation of medical devices Part 12: Test sample preparation and storage of materials)	A

Explanation:

1. Experiment environment

CELL LINE: L929 (Mouse Fibroblast cell)

Culture Medium : DMEM+ L-Glutamin

Fetal Bovine Serum

Penicillin- Streptomisin

Blank : Sterile cell culture medium

NEGATIVE CONTROL: Polietilen Kryo-Tüp + Cell

POSITIVE CONTROL: Natural Rubber Latex+ Cell

Report Number

- 2020-C-1099

On the other hand,

: 05/04/2020

2. METHOD OF APPLICATION

Extraction was performed according to TS EN ISO 10993-12 standard. The samples were placed in a waterbath at a rate of 50 rpm at 37°C for 24 hours in a 10% serum-containing cell culture medium of the size specified in the standard. The extraction was then terminated and the extract obtained was used within 24 hours.

ANALYSIS METHOD

Quantitative Evaluation:

Cells were expected to become confluent by seeding 6 well plates.

Subsequently, the 37°C 5% CO₂ sample was exposed to negative, positive control and sample extracts for 24 hours. After incubation, cells were microscopically examined and evaluated according to TS EN ISO 10993-5 standard.

Quantitative Evaluations

In the study, it was applied according to the TS EN ISO 10993-5 / XTT Cytotoxicity Experiment⁴ standard. The 96-well plate was counted as 100 / well and the cultured cells were incubated for 24 hours to provide 80% confluency. Subsequently, the cells were exposed to 1/1 - dilutions of the sample extract for 4 hours.

At the end of the process, 1 mg / mL XTT was added to the wells and the plates were incubated for 3 hours at 37 ° C in 5% CO₂. The assay was terminated by the addition of isopropyl alcohol to the wells and the % viability values were calculated by measuring the color change in the plates (570-630 nm) spectrophotometer.

4. TEST RESULTS

Qualitative Evaluation:

The qualitative evaluation was made according to Table 1 in TS EN ISO 10993-5 standard.

Must No.	Test Material	Reaction	Situations of Cultures
1	Negative Control	0	Discrete endoplasmic granules, cell disruption no, no decrease in cell proliferation
2	Positive Control	4	Nearly all cell layers have been destroyed
3	Sample	0	Discrete intraplasmic granules, no cell destruction, no decrease in cell proliferation

Report Number

: 2020-C-1089

Date of Report

:05/06/2020

Quantitative Evaluation:

(TS EN ISO 10993-5 / KTT Cytotoxicity Test)

Table 2: KTT Test results

DILUTION RATIOS						
TEST NUMBER	100%	75%	50%	25%		
1. AGAIN	0,963	1,111	1,245	1,345		
2. AGAIN	0,914	1,120	1,216	1,337		
3. AGAIN	0,946	1,114	1,224	1,359		
AVERAGE	0,941	1,115	1,228	1,337		
POSITIVE CONTROL	100%	75%	50%	25%		
1. AGAIN	0,104	0,206	0,321	0,426		
2. AGAIN	0,106	0,208	0,314	0,441		
3. AGAIN	0,108	0,201	0,325	0,405		
AVERAGE	0,106	0,205	0,320	0,424		
Negative Control(%100)	1.Again	2.Again	3.Again			
%100 Ekstrakt	1,109	1,111	1,112			
AVERAGE	1,11					
Blank	A2	A3	A4	A5	A6	A7
	0,888	0,990	0,999	0,996	1,010	1,002
	H2	H3	H4	H5	H6	H7
	0,991	0,992	0,994	0,999	1,080	1,099
AVERAGE	1,003					

$V_{lab. \%} = 100 \times OD_{450a} / OD_{450b}$

OD450a : % 100 optical density of the sample extract

OD450b : Average value of optical density of blank

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05/06/2020

Test Sample Viab.% : % 94

Positive Control Viab.% : % 11

Negative Control Viab.% : % 111

REVIEWS :

1.The test was carried out in accordance with the standard "TS EN ISO 10993-5 Biological evaluation of medical devices-Part 5: extracorporeal cytotoxicity tests".

2.The effect of the extracts on the cells for qualitative evaluation was examined microscopically and evaluated by the qualitative morphological grading of the cytotoxicity of the extracts given in the standard "Table 1. Accordingly, the negative control showed no toxic effect on the cells (0), and the positive control showed toxicity as high as expected (4). Since the cytotoxic effect of the sample extracts was not toxic when examined, it was evaluated as (0). According to the standard used, as indicated in table 1, the presence of a larger rating value of (2) is considered a cytotoxic effect.

3.The "TS EN ISO 10993-5 / XTT Cytotoxicity Experiment" was used as the quantitative evaluation method and the obtained results (Table 2) were evaluated statistically. Results from the negative and positive controls used and test validity criteria are met.

In this experiment, the effects of 1/1 dilutions of sample extract on cells were examined; The complete dilution of extract from the sample (1/1) and viability was 94%.

According to the standard used, this value is less than 70%, indicating that there is no cytotoxic effect on the sample extracts since there is a cytotoxicity indicator.

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:05/06/2020

Chart1. Qualitative morphological grading of cytotoxicity of extracts

Degree	Reaction	Situations of Cultures
0	No	Discrete intracellular granules, no cell destruction, no decrease in cell proliferation
1	Very little	There are more than 20% of cells that are not round, poorly adherent, and contain few or no intracellular granules, or morphologically altered, rarely destroyed cells, only slight growth inhibition can be observed
2	Light	Round cell number is less than 50%, no intracellular granules, observable cell inhibition is not more than 60%
3	Middle	The number of cells rounded or destroyed is not more than 70%, the cell layers are not completely degraded, the observable cell inhibition is more than 50%
4	Severe	Nearly all cell layers have been destroyed

(*) Analysis method is in scope of accreditation.

Evaluation

The above mentioned issues were determined as the result of the sample and analysis.

1. No part of this analytical report can be used alone or separately. Unsigned and unsealed reports are not valid.

2. Analysis results are valid for the above sample.

3. When necessary, "Measurement Uncertainty" and "Recovery" information is given together with the analysis results.

4. Judicial and administrative procedures can be used for advertising purposes. It can not be partially reproduced and published without the permission.

Abbreviations: ND: Not Detected A: Appropriate IA: Inappropriate AF: Assessment Failed EVL: Evaluation

Cell Microbiology Unit Responsible
Hüsnü Lami Demir (v)

Responsible of the Department of Sample and Method
Hüsnü AŞCI

Approved by
05/06/2020
Mehmet Nur ERAT
Laboratory Manager

LABORATUVAR HİZ. FİD. LTD. STİ
Atatürk Bulvarı Kat: 10. Kat
34500 Büyükdere / İstanbul
Tic. Sic. No: 275115
Tic. Sic. No: 275115

Report No: 2020170631
Applicant: MY TİCARET VE MEDİKAL A.Ş.
Ömerli mah. General Şükrü Koralı cad. No:33 Arnavutköy/ İstanbul
Contact Person: Z. Melek ÖZ BOLAT
Contact Telephone: 0212 438 2064
Contact e-mail: info@mymedikal.com.tr / kalite@mymedikal.com.tr
Sample Accepted on: 10.06.2020
Report Date: 17.06.2020
Total number of pages: 9 (Pg)
Sample ID: Surgical Mask

	TEST	METHOD	Specimen	RESULT
*	Medical and surgical face masks - Requirements and test methods	EN 14683+AC 2019	Surgical Mask	PASS
				TYPE IIR



Seal

Customer Representative
Mehmet KUTLULaboratory Manager
Hakan SARILAYDIN

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Environment

The requirements and standards apply to equipment intended for use in

X	Residential (domestic) environment
X	Commercial and light-industrial environment
X	Industrial environment
X	Medical environment

Requirements and test methods

This European Standard specifies construction, design, performance requirements and test methods for medical face masks intended to limit the transmission of infective agents from staff to patients during surgical procedures and other medical settings with similar requirements. A medical face mask with an appropriate microbial barrier can also be effective in reducing the emission of infective agents from the nose and mouth of an asymptomatic carrier or a patient with clinical symptoms.

General

All tests shall be carried out on finished products or samples cut from finished products, if applicable in their sterile state.

Method for In-vitro determination of bacterial filtration efficiency (BFE)**Principle**

A specimen of the mask material is clamped between a six-stage cascade impactor and an aerosol chamber. An aerosol of *Staphylococcus aureus* is introduced into the aerosol chamber and drawn through the mask material and the impactor under vacuum. The bacterial filtration efficiency of the mask is given by the number of colony forming units passing through the medical face mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol.

Reagents and materials**General**

Describe commercially available solutions of tryptic soy agar and tryptic soy broth. Other variants may be suitable.

Tryptic soy agar**Formula/liter:**

Enzymatic digest of casein	15 g
Enzymatic digest of soybean meal	5 g
Sodium chloride	5 g
Agar	15 g
Final pH	7,3 ± 0,2 at 25 °C

Tryptic soy broth

Formula/iter:

Enzymatic digest of casein	17 g
Enzymatic digest of soybean meal	3 g
Sodium chloride	5 g
Dextrose	2,5 g
Final pH	7.3 ± 0.2 at 25 °C

Peptone Water

Formula/liter:

Peptone	1 g
Sodium chloride	5 g
Final pH	7,3 ± 0,2 at 25 °C

Preparation of bacterial challenge

Staphylococcus aureus shall be inoculated into 30 ml tryptic soy broth in an Erlenmeyer flask and incubated with mild shaking at a temperature of $(37 \pm 2) ^\circ\text{C}$ for (24 ± 2) h. The culture shall then be diluted in peptone water to give a concentration of approximately 5×10^5 cfu/ml.

The bacterial challenge shall be maintained at $(2\ 200 \pm 500)$ cfu per test. The bacterial challenge shall be determined on the basis of experience and previous positive control plates (see 8.6.3) and the dilution of the challenge suspension adjusted accordingly. The mean particle size in the bacterial challenge shall be maintained at $(3,0 \pm 0,3)$ μm (see 8.6.9).

Procedure

Assemble the apparatus in accordance with the flow chart shown in Figure B.1.

Deliver the bacterial challenge to the nebulizer using the peristaltic or syringe pump.

Perform a positive control run without a test specimen. Initiate the bacterial challenge by turning on the vacuum pump and adjust the flow rate through the cascade impactor to 28,9 l/min. Deliver the bacterial challenge for 1 min. Maintain the airflow through the impactor for 2 min. Then remove the plates from the impactor. Ensure that each plate is numbered to indicate its position in the impactor.

Place fresh plates in the impactor, fix a test specimen in place and repeat the above procedure.

Repeat this procedure for each test specimen.

After the last test specimen has been tested, perform a further positive control run.

Perform a negative control run by passing air, without addition of the bacterial challenge, through the cascade impactor for 2 min.

incubate all the plates at $(37 \pm 2)^\circ\text{C}$ for (48 ± 4) h.

For each specimen and control run, count the number of colonies on each plate and add up the counts to give the total number of cfu collected by the impactor using the "positive hole" conversion table1) in accordance with the instructions of the cascade impactor manufacturer. For the two positive control runs, take the mean of the two totals. From the positive control plates calculate the mean particle size of the bacterial challenge aerosol using the "positive hole" conversion table in accordance with the instructions of the cascade impactor manufacturer.

Calculation of bacterial filtration efficiency

For each test specimen calculate the bacterial filtration efficiency B, as a percentage, using the following formula:

$$B = (C - T) / C \times 100$$

Where;

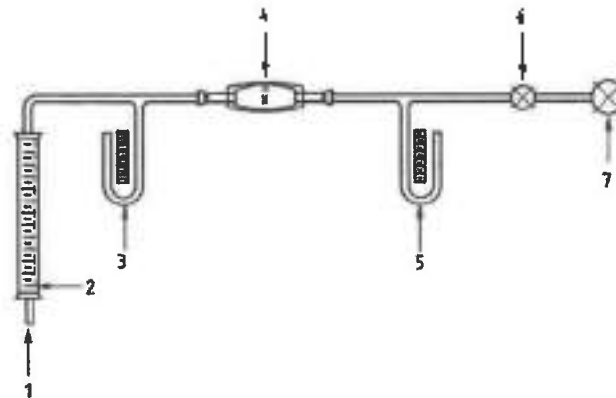
C is the mean of the total plate counts for the two positive control runs;

T is the total plate count for the test specimen.

Method for determination of breathability (differential pressure)

Principle

A device which measures the differential pressure required to draw air through a measured surface area at a constant air flow rate is used to measure the air exchange pressure of the medical face mask material, as shown in Figure 1. Water-filled manometers (M1 and M2) are used to measure the differential pressure. A flow meter is used for measurement of the airflow. An electric vacuum pump draws air through the apparatus and a needle valve is used to adjust the airflow rate.



Key

1 air inlet

2 flow meter

3 manometer M1

4 filter material

5 manometer M2

6 valve

7 vacuum pump

Figure 1 — Apparatus for measuring air resistance

Procedure

The test specimen is placed across the 2,5 cm diameter orifice (total area 4,9 cm²) and clamped into place so as to minimise air leaks and that the tested area of the specimen will be in line and across the flow of air.

The pump is started and the flow of air adjusted to 8 l/min.

The manometers M1 and M2 are read and recorded.

The procedure described in steps 1 through 3 is carried out on 5 (or appropriate number of) different areas of the mask and the readings averaged.

Calculation of differential pressure

For each test specimen calculate the differential pressure ΔP as follows:

$$\Delta P = (X_{m1} - X_{m2}) / 4,9$$

Where;

X_{m1} is pressure in Pa, manometer M1, mean of 5 test areas, low pressure side of the material;

X_{m2} is pressure in Pa, manometer M2, mean of 5 test areas, high pressure side of the material;

4,9 is the cm² area of the test material;

ΔP is the differential pressure per cm² of test material expressed in Pa.

Splash resistance

When tested in accordance with ISO 22609 the resistance of the medical face mask to penetration of splashes of liquid shall conform to the minimum value given for Type IIR in Table 1.

Microbial cleanliness (Bioburden)

When tested according to EN ISO 11737-1 the bioburden of the medical mask shall be ≤ 30 cfu/g tested (see Table 1).

To determine the mask's bioburden according to EN ISO 11737-1, follow the procedure below:

The number of masks that shall be tested is minimum 5 (five), but can be greater if necessary to allow for an AQL of 4 %.

Weigh each mask prior testing. The full mask is aseptically removed from the packaging and placed in a sterile 500 ml bottle containing 300 ml of extraction liquid (1 g/l Peptone, 5 g/l NaCl & 2 g/l polysorbate surfactant 20 (e.g. Tween 20, Alkest TW 20)).

The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm. After this extraction step, 100 ml of the extraction liquid is filtered through a 0,45 μ filter and laid down on a TSA plate for the total viable aerobic microbial count. Another 100 ml aliquot of the same extraction liquid is filtered in the same way and the filter plated on Sabouraud Dextrose agar (SDA) with chloramphenicol for fungi enumeration. The plates are incubated for 3 days at 30 °C and 7 days at (20 – 25) °C for TSA and SDA plates respectively.

The total bioburden is expressed by addition of the TSA and SDA counts.

In the report, indicate the total bioburden per mask and based on the mask weigh, the total bioburden per gram tested.

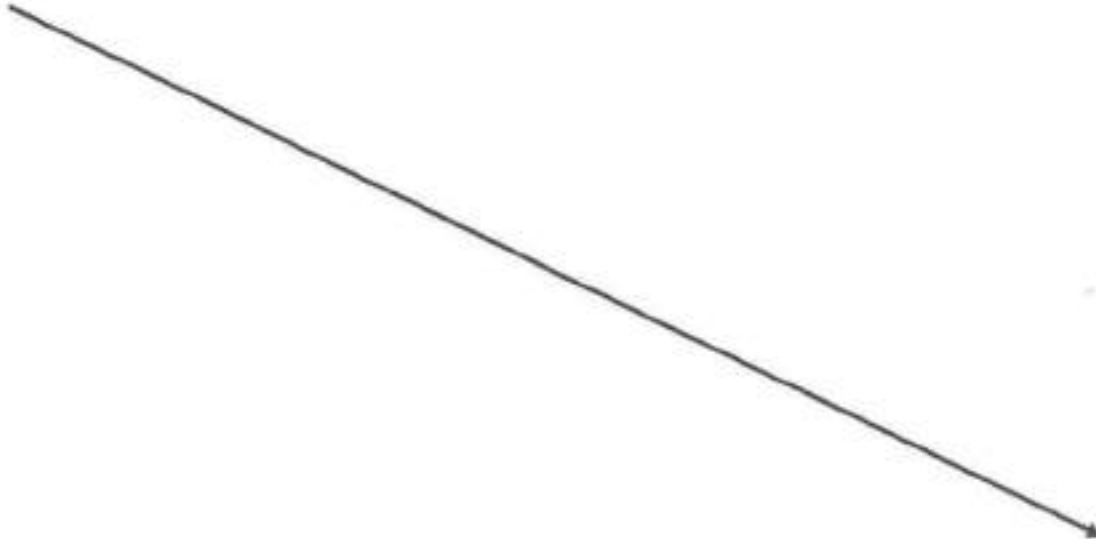
TEST REQUIREMENTS

Test	Type I ^a	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	≥ 16,0
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30

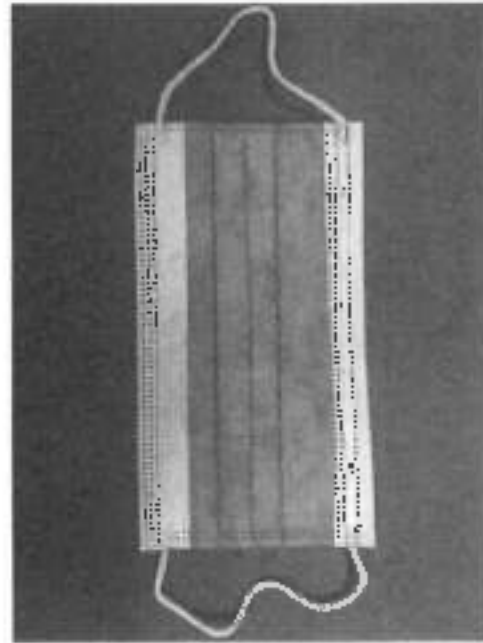
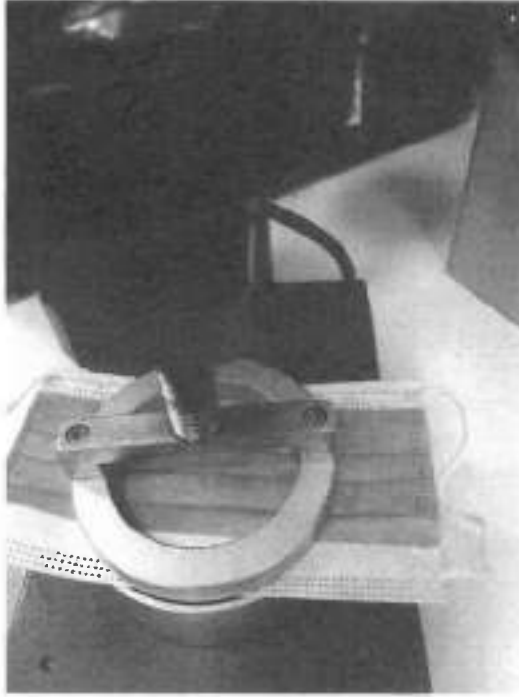
^a Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

TEST RESULTS
EN 14683 Inspection
SAMPLE : SURGICAL MASK

Test	Type			Result		Evaluation
Bacterial filtration efficiency (BFE), (%)	1 ≥ 95	2 ≥98	3 ≥98	98,86	98.97	PASS
				99,01		
				98,92		
				99,03		
				99,04		
Differential pressure (Pa/cm2)	< 40	<40	<60	21		PASS
Splash resistance pressure (kPa)	N/A	N/A	≥16,0	18		Type IIR
Microbial cleanliness (cfu/g)	≤ 30			21		PASS


Free Area

MASK IMAGES UNDER TEST



*****End of Report*****



**EKOTEKS LABORATUVAR ve GÖZETİM
HİZMETLERİ A.Ş.**
Esenyurt Finişköy Bulvarı No:29 34325 Avcılar
İstanbul/ TÜRKİYE



**TEST REPORT
DENEY RAPORU**

AB-0583-T

20018616-
Ing

06-20

EKOTEKS

Customer name: MY TİCARET VE MEDİKAL A.Ş.
Address: Ömerli Mahallesi General Şükrü Koralı Caddesi No:33 ARNAVUTKÖY/
İSTANBUL
Buyer name: -
Contact Person: Z.MELEK ÖZ BOLAT
Order No: -
Article No: -
Name and Identity of test item: One sample of white elastic cord.
The date of receipt of test item: 10.06.2020
Re-submitted/re-confirmation date: -
Date of test: 10.06.2020-17.06.2020
Remarks: -
Sampling: The results given in this report belong to the received sample by vendor.
End-Use: -
Care Label: Not specified.
Number of pages of the report: 3

The Turkish Accreditation Agency (TÜRKAK) is signatory to the multilateral agreements of the European co-operation for the Accreditation (EA) and of the International Laboratory Accreditation (ILAC) for the Mutual recognition of test reports.

EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş. accredited by TÜRKAK under registration number [AB-0583-T] for ISO 17025:2017 as test laboratory.

The test and/or measurement results, the uncertainties (if applicable) with confidence probability and test methods are given on the following pages which are part of this report.

Seal

Date
18.06.2020

Customer Representative
Özlem ULUS

Head of Testing Laboratory
Sevim A. RAZAK

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HİZMETLERİ A.Ş.**

AB-0583-T

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06-20

REQUIRED TESTS	RESULT	COMMENTS
PHYSICAL PROPERTIES TESTS		
Determination of Material	-	
No requirement was given.		

REMARK: Original samples are kept for 3 months and all technical records are kept for 5 years unless otherwise specified. If requested, measurement uncertainty will be reported. But unless otherwise specified, measurement uncertainty is not considered while stating compliance with specification or limit values. The reported uncertainty is based on a standard uncertainty multiplied by a coverage factor $k=2$, providing a level of confidence of approximately 95 %. Tests marked (*) in this report are not included in the accreditation schedule.



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AB-0583-T

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06-20

TEST RESULTS

DETERMINATION OF MATERIAL: EKOTEKS 40

FT-IR. Spectrophotometer Test Machine.

RESULT
Polyurethane

REQUIREMENT

-

Note: The test result was identified as Polyurethane using by FT-IR spectrometer method which is based on to compare with the reference material. The similarity of the test sample to reference is %73 was found.

Note: Latex does not contains.



INSTRUCTIONS FOR USE

MUMU 3-PLY SURGICAL MASK

(FACIAL MASK FOR MEDICAL USE)

Intended Use:

3-ply surgical masks (facial mask for medical use) is intended to be worn by medical personnel during surgical or other medical procedures to protect both the patient and the operating personnel and any other person that want and need to be protected, from transfer of microorganisms, body fluid, particulate material transfer and any other microbes.

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

Technical Specifications:

Non-irritating, Fluid Resistant, Three Ply construction.

3 pleats of folds to allow the user to expand the mask so it covers the area from the nose to the chin. Mask is secured with an ear loop to be placed behind the ears.

The surgical mask's (facial mask for medical use) 3-ply layers work as follows:

- **The outer layer** repels water, blood, and other body fluids.
- **The middle layer** filters certain pathogens.
- **The inner layer** absorbs moisture and sweat from exhaled air.

Donning The Mask:

- Before putting on the mask, wash your hands for at least 20 seconds with soap and water, or rub your hands together thoroughly with alcohol-based hand sanitizer.
- Check for defects in the face mask, such as tears or broken loops.
- Position the colored side of the mask outward.
- If present, make sure the metallic strip is at the top of the mask and positioned against the bridge of your nose.
- Ear loops: Hold the mask by both ear loops and place one loop over each ear.
- Mold the bendable metallic upper strip to the shape of your nose by pinching and pressing down on it with your fingers.
- Pull the bottom of the mask over your mouth and chin.



- Be sure the mask fits snugly.
- Don't touch the mask once in position.
- If the mask gets soiled or damp, replace it with a new one.

!! Do not:

- touch the mask once it's secured on your face, as it might have pathogens on it
- dangle the mask from one ear
- hang the mask around your neck
- reuse single-use masks.

If you have to touch the face mask while you're wearing it, wash your hands first. Be sure to also wash your hands afterward, or use hand sanitizer.

Doffing The Mask:

- Before you take off the mask, wash your hands well or use hand sanitizer.
- Avoid touching the mask itself, as it could be contaminated. Hold it by the loops, ties, or bands only.
- Carefully remove the mask from your face once you: unhook both ear loops.
- Holding the mask loops discard the mask by placing it in a covered trash bin.
- After removing the mask, wash your hands thoroughly or use hand sanitizer.

STORAGE

Capable of being stored continuously in ambient temperature of 10 to 35 deg C and relative humidity of 15 to 55%. Capable of operating continuously in ambient temperature of 10 to 35 deg C and relative humidity of 15 to 55%.

It is recommended that 3-ply surgical masks (facial mask for medical use) should be stored in their original containers and should be stored away from direct sunlight, heat sources and liquids, including chemicals. The area should be clean and should protect the masks from contamination. Never store it in a purse or pocket.

