mumu

3-ply Surgical Kid's Mask With Earloop

EN 14683:2019+ AC:2019 Tip/Type IIR;BFE % ≥ 98

PURPOSE OF USE

Surgical kid's mask can be used for hygenic applications. Suitable for useby kids.
Made of non- woven fabric.
Air permeable structure allows easy breathing.
Produced with food contact paints.
Does not contain allergic materials.
3-ply structure. Non irritating.

KIDS

Filtered and 3 - Ply

Compatible Tire

Certificate of Registration

MANAGEMENT SYSTEM
ISO/IEC 17021-1:2015
NAC-002-MS

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

This certificate is valid concerning all activities related to;

PRODUCTION AND SALE OF LATEX POWDERED / POWDER FREE EXAMINATION GLOVES, NITRILE POWDER FREE EXAMINATION GLOVES, STERIL / NON-STERILE SURGICAL GLOVES, STERIL / NON-STERILE SPONGE GAUZE COMPRESS, STERIL / NON-STERIL COMPRESSE ABDOMINALE, STERIL / NON-STERILE COTTON PAD, GAUZE, STERILE / NON-STERILE SURGICAL MASK

LATEKS PUDRALI / PUDRASIZ MUAYENE ELDiVENi, NiTRiL PUDRASIZ MUAYENE ELDiVENi, STERiL / NON-STERiL CERRAHi ELDiVEN, STERiL / NON-STERiL SPANÇ GAZ KOMPRES, STERiL / NON-STERiL BATIN KOMPRES, STERiL / NON-STERiL PAMUKLU PED, GAZLI BEZ,
STERiL / NON-STERiL CERRAHi MASKE ÜRETİMİ VE SATIŞI

ISO 01 940 1179	Jun. 5, 2020	Jun. 4, 2021
Certificate No.	*Date of this Certificate*	*Certification Expiry Date*
May. 28, 2020	Jun. 5, 2020	
Date of Audit	*Date of Registration*	*Managing Director / Director*

MDC MEDICERT CERTIFICATE

Certificate of Registration

ACCREDITED BY NAC
MANAGEMENT SYSTEMS
ISO/IEC 17021-1:2015
NAC-002-MS

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;

SALES OF LATEX POWDERED / POWDER-FREE EXAMINATION GLOVES- NITRILE POWDER-FREE EXAMINATION GLOVES- POWDERED / POWDER-FREE STERILE SURGICAL GLOVES-VINYL POWDERED / POWDER-FREE EXAMINATION GLOVES. PRODUCTION AND SALE OF DISPOSABLE NON-STERILE MASKS.

LATEKS PUDRALI/PUDRASIZ MUAYENE ELDİVENİ- NİTRİL PUDRASIZ MUAYENE ELDİVENİ- PUDRALI/PUDRASIZ STERİL CERRAHİ ELDİVEN-VİNİL PUDRALI/PUDRASIZ MUAYENE ELDİVENİ SATIŞI. TEK KULLANIMLIK NON-STERİL MASKE ÜRETİMİ VE SATIŞI.

ISO 02 836 1179	Feb. 26, 2020	Feb. 25, 2021
Certificate No.	*Date of this Certificate*	*Certification Expiry Date*
Feb. 21, 2020	Feb. 26, 2020	
Date of Audit	*Date of Registration*	*Managing Director / Director*

MDC MEDICERT CERTIFICATE

Certificate of Registration
2020

This is to certify that the registration of

MY TICARET VE MEDIKAL A.S
OMERLI MAH. GENERAL SUKRU KORALTI CAD. NO: 33 ARNAVUTKOY,
ISTANBUL, TURKEY - 34555

with U.S. Food and Drug Administration as required by 21 CFR Part 807 is successfully completed by Liberty Management Group Ltd with the information provided by My Ticaret Ve Medikal A.S

Owner/Operator Number	**10075681**
Date of Registration	**June 23, 2020**
Date of Expiration	**December 31, 2020**
US Agent	**Liberty Management Group Ltd.**
Device Listing Numbers	**See Annex**
Certificate Number	**3006230220**

This certificate does not make representations or warranties to any person or entity other than the named certificate holder; it is issued for record keeping purpose only. This certificate does not denote endorsement or approval of certificate holder's facility or product by the U.S. food and Drug Administration. Liberty management Group Ltd. assumes no liability to any person or entity in connection with the foregoing.

The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Liberty Management Group Ltd. is not affiliated with the U.S. Food and Drug Administration.

LMG LIBERTY MANAGEMENT GROUP LTD.
75 Executive Drive, Aurora, Illinois, USA
www.fdahelp.us

Manoj Zacharias
President
Liberty Management Group LTD.
Dated: June 23, 2020

Certificate of Registration
2020

Annex - Device Listings

Listing Number	Code	Device Name - Proprietary Names
D409537	QKR	Face mask (except N95 respirator) for general public/healthcare personnel per IIE guidance - Mumu Surgical Mask

EC DECLARATION OF CONFORMITY

MY Medikal

Manufacturer's Name:	MY TICARET VE MEDIKAL A.Ş.
Manufacturer Address:	Ömerli Mah. General Şükrü Koraltı Cad. No: 33 Arnavutköy / Istambul
Medical Devices:	Surgical Mask. 3-ply with earloop Ref No: MM.NS.LM.01
Classification:	Medical Device Directive-Annex IX. Rule I. Class-1 (Type IIR)
GMDN Code and Term:	57794 /Surgical Medical Respirator
Scope of Application:	All batches supplied to which the Declaration of Conformity Procedur 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 out products comply with EN 14683:2019+AC: 2019 as Type IIR
Verification Certificates:	Quality Management System- Medical devices EN ISO-13485:2016 ' Certificate No: ISO 02 836 1179 Quality Management System EN ISO 9001:2015 Certificate No: ISO 01 940 117
Standards Applied:	**EN ISO 13485** Medical devices-Quality management systems - Requirements for regulatory purposes **EN ISO 9001:2015** Quality management systems **EN ISO 15223-1** Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied **MDD 93/42/EEC** Medical devices directive **EN ISO 1041** Information supplied by the manufacturer of medical devices **EN ISO 14683:2019+AC: 2019** Medical face masks - Requirements and test methods **EN ISO 62366-1** Medical devices - Part 1: Application of usability engineering to medical devices **EN ISO 14971** Medical devices - Application of risk management to medical devices

Authorised Signatory

Name-Surname:	**Murat YILDIZ**
Position :	**CEO**
Signed:	MY TİCARET VE MEDİKAL ANONİM ŞİRKETİ Ömerli Mah. General Şükrü Koraltı Cad. No: 33 Arnavutköy / İSTANBUL Büyükçekmece V.D.: 626 040 4605 Tel: 0212 438 20 64 Fax: 0212 438 20 65 www.mymedikal.com.tr
Dated:	**22.03.2020**

CE

TECHNICAL FILE

MUMU SURGICAL MASKS

MY Medikal

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

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 MEDIKAL :

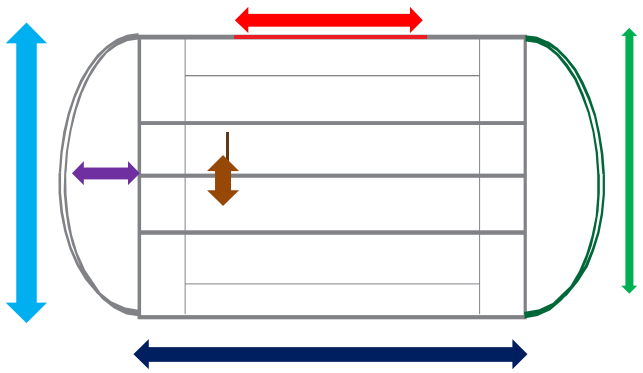
MY TICARET VE MEDIKAL has been manufacturing its products with the quality systems as given below;

- 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 wowen 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	**Body Size**	**Length**	175 mm
		Width	95 mm
	Height of Earloop		70 mm
	Lenght of Earloop		160 mm
	Pleat Depth		10 mm
	Length of Nose-piece		90 mm

Dimension (Infant)	**Body Size**	**Length**	145 mm
		Width	95 mm
	Height of Earloop		70 mm
	Lenght of Earloop		160 mm
	Pleat Depth		10 mm
	Length of Nose-piece		60 mm

3. SUBSTANCE/MIXTURE OF RAW MATERIAL :

Characteristic	**Specification**		
Materials			
	Mask Body	Outer Material	Spunbond 25 -30 gr
		Filter Layer	Meltblown 25 gr
		Inner Material	Spunbond 20-25 gr

3.1.Material Safety Data Sheet (MSDS)

3.1.1. Composition:

Idendification 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 1°/0 ..... *No.
Binder..... *No
Additives ..... Yes.
May contain color pigments if the product is in color. White color may contain Ti02.
Other major components ..... *No
Chemicals (in relevant concentration) that are in list of dangerous substances.....*.No

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

Undernormal 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. Extinguishingmedia not to be used..... None

3. Special exposure hazards ..... For flammable and toxic fumes as well as skin contact with molten materials see Ş 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
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
Vapourpressure .....Not applicable
Static electricity .....The product can develop and/or accumulate static electricity, (i.e. by rubbingor friction)
Solubility..... Mater 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. Underdecomposition 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.

3.2.Technical Data Sheet and Certficate

TECHNICAL DATA SHEET

Product	Polypropylene
Product Description	ENDLESS FILAMENTS SPUNBOND, THERMALLY BONDED
Raw Material	100 % PP
Applicances on Fabric	SS :HYDROPHOBIC
Treatment	
Fabric Colour	WHITE
Customer Name	
Weight	25 GSM
Width	
Packing	PE BAG WITH LABEL

PROPERTIES		TEST METHOD	UNIT	TARGET
WEIGHT		NWSP 130.1.R0 (15)	gsm	25
THICKNESS		NWSP 120.1.R0 (15)	mm	0.28
TENSILE STRENGTH	MD	NWSP 110.4.R0 (15)	N/5 cm	35,0
	CD			25,0
ELONGATION AT BREAK	MD	NWSP 110.4.R0 (15)	%	118,0
	CD			114,5

Tolerances For The Average Results

Weight	± 5 %
Thickness	± 10 %
Tensile Strenght	± 15 %
Elongation	± 15 %
Hydrostatic Head	± 15 %
Liquid Strike-Through Time	± 0,5 %
Air Permeability	± 20 %
Absorption	± 20 %

Roll Tolerance

Length : - 0 / +5% against target / ordered lenght
Width : Up to 150 cm in width = -0mm/+5mm Over 150 cm in width = - 0mm/+10
Splice : Maximum five splices per roll

The product is wound onto cardboard cores and then wrapped in polyethylen film. Bar code labels with product code, description and lot details are applied to the outside of each pack and a small label is applied to each roll. Suitable sized rolls may be palletised and the pallet load cling-wrapped

Preparation Date	QUALITY CONTROL APPROVAL
01.04.2020	

HOHENSTEIN Textile Testing Institute GmbH & Co. KG
Schloßstraße 1, 74357 Bönnigheim, Germany

OEKO-TEX®
INSPIRING CONFIDENCE

CERTIFICATE

The company

BAYTEKS TEKNIK TEKSTIL SAN. VE TIC. A.S.
Organize Sanayi Bölgesi 19 Nolu Cadde No. 9
79000 Merkez - Kilis, TURKEY

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

is granted authorisation according to STANDARD 100 by OEKO-TEX® to use the STANDARD 100 by OEKO-TEX® mark, based on our test report
19.0.01029

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 waste), with and without PE lamination (in colour white and blue) and additives including UV stabiliser.

The results of the inspection made according to STANDARD 100 by OEKO-TEX®, Appendix 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 Appendix 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.MO.41419 is valid until 31.03.2021

Boennigheim, 28.01.2020

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

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 and adult). Because all of the products are made from the same raw materials.

Parameters	Units	Method	Results	Test Results
BFE (Filtration)	%	Internal method based on EN 14683:2019+AC:2019	≥98	% 98,97 (Eurolab-2020170631)
Differencial pressure (Breathability)	Pa/cm2	Internal method based on EN 14683:2019+AC: 2019	<40	21 (Eurolab-2020170631)
Microbial cleanliness / bioburden	UFC/g	ISO 11737-1:2018	≤30	21 (Eurolab-2020170631)
Splash resistance pressure	kPa	ISO 22609	≥16	18 (Eurolab-2020170631)
Biocompatibility		ISO 10993-1	Suitable for skin Cytotoxicity, Irritation, Sensitization	Cytotoxicity: It is not cytotoxicity. (Oxigen-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

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.

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 hygneic 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**
	**Referance 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%.

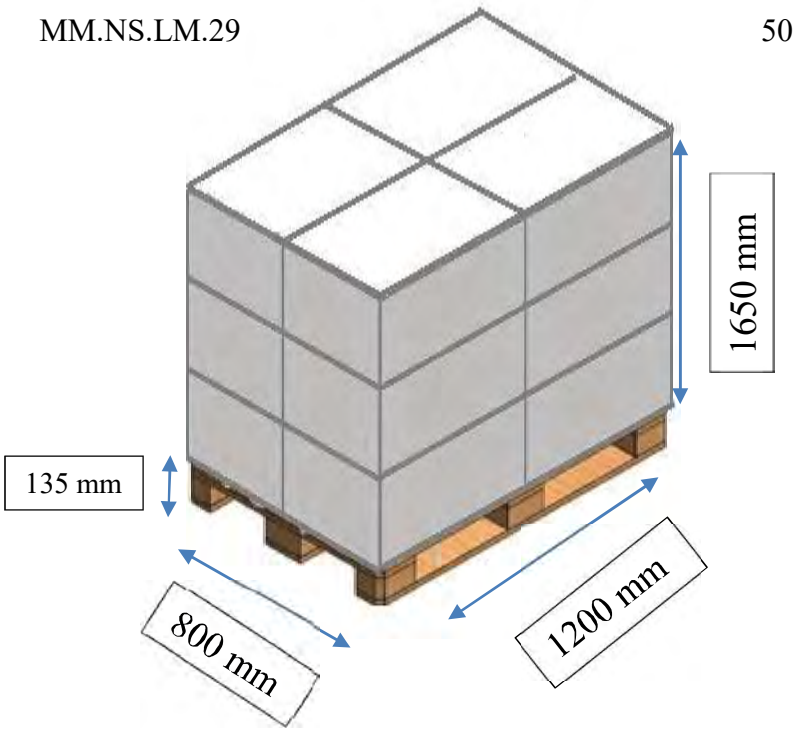
It is recommended that surgical face masks (facial mask for medical use)should be stored in their original containers and should be stored away from direct sunlight, heat sources and liquids, including chemicals. The area should be clean and should protect the masks from contamination. Never store it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

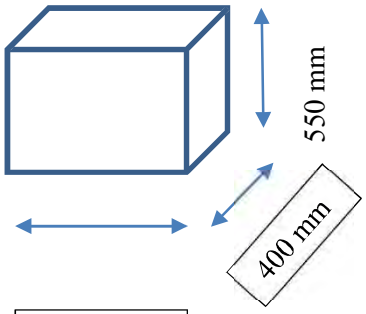
12. SAFETY INFORMATION :

- 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

Ref. No.	Quantity per Box
MM.NS.LM.01	50 pcs
MM.NS.LM.29	50 pcs





Quality Assurance Manager

Vedat ÇETİN

MY TİCARET VE MEDİKAL ANONİM ŞİRKETİ

OXIGEN ANALİZ ÖZEL KONTROL LABORATUVARI
Çakmaklı Mah. Hadımköy Bağlantı Yolu Ufuk Plaza
No:57 K:1 D:8 34500 Büyükçekmece/İSTANBUL

TÜRKAK
TÜRK AKREDİTASYON KURUMU
Tarafından Akredite Edilmiştir.

MUAYENE VE ANALİZ RAPORU

Test
TS EN ISO/IEC 17025
AB-0953-T

AB-0953-T
2020-C-1099
06-2020

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

Purpose of Analysis : Cytotoxicity Test

Costumer name/addres : MY Ticaret ve Medikal. A.S. / Ömerli Mah. Genral Sükrü Koralti Cad. No:33 / ISTANBUL

Name andidentity 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	Uncertainity of Meas.	Analysis Metod	Com.
1-*InvitroCytotoxicity Test		it is not Cytotoxicity				TS EN ISO 10993-5((Biologicalevaluation in medicaldevicesPart 5: Test for in vitrocytotoxicity TS EN ISO 10993-12 (Biologicalevaluation in medicaldevicesPart 12: Test samplepreparationand Reference Materials..	A

Explanation:

1. Experiment environment

CELL LINE:L929 (Mouse Fibroblast cell)

CultureMedium : DMEM+ L-Glutamin
Fetal Bovine Serum

Penisilin- Streptomisin

Blank : Sterile cell culture medium

NEGATIVE CONTROL: Polietilen Kryo Tüp + Cell

POSITIVE CONTROL: Natural RubberLatex+ Cell

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

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 cellculture medium of the size specified in the standard. The extraction was then terminated and the extract obtained was used within 24 hours.

3.ANALYSIS METHOD

Qualitative Evaluation:

Cells were expected to become confluent by sowing 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 ande valuated according to TS EN ISO 10993-5 standard.

Quantitative Evaluation:

In the study, it was applied according to the "TS EN ISO 10993-5 / XTT Cytotoxicity Experiment" 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 (570-650 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	Discreteendoluminalgranules, celldisruptionno, nodecrease in cellproliferation
2	Positive Control	4	Nearlyallcelllayers have been destroyed
3	Sample	0	Discreteintraoplasmagranules, no cell destruction, no decrease in cell proliferation

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

Quantitative Evaluation:

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

Table 2. XTT 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					

Viab.%=100 X OD450e/OD450b

OD450e : % 100 optical density of the sample extract

OD450b : Average value of optical density of blank

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

Test SampleViab.% : % 94

PozitiveControlViab.% :% 11

Negative ControlViab.% : %111

REVIEWS :

1.The test was carried out in accordance with the standard "TS EN ISO 10993-5 Biologicalevaluation of medicaldevices-Part 5: extracorporealcytotoxicitytests".

2.The effect of the extracts on the cells for qualitative evaluation was examined microscopically andevaluatedbythequalitativemorphologicalgrading of thecytotoxicity of theextractsgiven 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 thecytotoxiceffect of thesampleextractswas not toxicwhenexamined, it wasevaluated as (0).Accordingtothestandardused, as indicated in table 1, the presence of a larger rating value of (2) is considered a cytotoxiceffect.

3.The "TS EN ISO 10993-5 / XTT Cytotoxicity Experiment" wasused 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 extractfromthesample (1/1) andviability was **94%.**

According to the standard used, this value is lessthan 70%, indicatingthatthere is nocytotoxiceffect on thesampleextracts since there is a cytotoxicityindicator.

OXIGEN ANALİZ ÖZEL KONTROL LABORATUVARI
Çakmaklı Mah. Hadımköy Bağlantı Yolu Ufuk Plaza
No:57 K:1 D:8 34500 Büyükçekmece/İSTANBUL

TÜRKAK
TÜRK AKREDİTASYON KURUMU
Tarafından Akredite Edilmiştir.

MUAYENE VE ANALİZ RAPORU

Test
TS EN ISO/IEC 17025
AB-0953-T

AB-0953-T
2020-C-1099
06-2020

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

Chart1. Qualitative morphological grading of cytotoxicity of extracts

Degree	Reaction	Situations of Cultures
0	No	Discreteintraoplasma 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 morphologicallyaltered, rarely destroyed cells, only slight growth inhibition can be observed
2	Light	Round cell number is less than 50%, nointraplosiongranules, observable cell inhibition is not more than 50%
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 acreditation.
Evaluation:
Theabovementionedvalueswereddetermined as theresultof theinspectionandanalysis.
1.No part of thisanalyticalreport can be usedaloneorseparately. Unsignedandunsealedreportsaredefund.
2.Analysis resultsarevalidfortheabovesample
3.When necessary, "MeasurementUncertainty" and "Recover" informationaregiventogetherwiththeanalysisresults
4.Judicial andadministrativeproceduresto be usedforadvertisingpurposes. It can not be partiallyreproducedandpublishedwithoutpermission

Abbreviations: N.A: Not Detected A:Appropriate IA: Inappropriate AF: AssessmentFailedEVL :Evaluation

Çel Microbiology Unit Responsible
Havva Lamia Demir

Responsible of theDepartment of SampleAdmission
Nilsun AŞÇI

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

oxigen
LABORATUVAR HİZ. TİC. LTD. ŞTİ.
Mah. Hadımköy Bağlantı Yolu Ufuk Plaza
2 No:8 B.Çekmece-İSTANBUL / TURKIYE
Tel:+90 212 886 85 05 - 08

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 Koraltı 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 ☒ Archieved
	Not received ☐

Figure 1: Image of the product

Signatures of Researchers in Charge of the Test

Institutional Registry No: 975	Institutional Registry No: 2021	Institutional Registry No: 2486
Signature	Signature	Signature

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

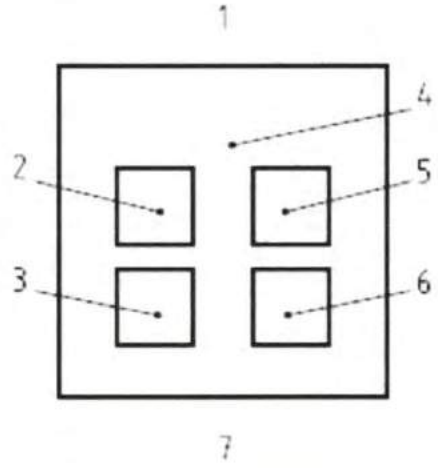
The irritation test reported here was applied according to the "ISO 10993 -10:2014 Biological Evaluation of Medical Devices- Part 10: Tests for İrritation and Skin Sesnsitization, ISO 10993-2:2006 Animal Welfare Requirements and ISO-10993-12:2013Sample Preparation and Reference Materials'' standards.

Signatures of Researchers in Charge of the Test

Institutional Registry No: 975	Institutional Registry No: 2021	Institutional Registry No: 2486
Signature	Signature	Signature

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



1- Cranial

2- Test Area-I

3- Negative Control Site

4- Shaved Dorsal Region (rabbit healthy control)

5- Positive Control Site

6- Test Area-II

7- Caudal

Figure 3: Rabbit Skin Irritation Test Regions

Signatures of Researchers in Charge of the Test

Institutional Registry No: 975	**Institutional Registry No: 2021**	**Institutional Registry No: 2486**
Signature	**Signature**	**Signature**

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

Signatures of Researchers in Charge of the Test

Institutional Registry No: 975
Signature

Institutional Registry No: 2021
Signature

Institutional Registry No: 2486
Signature

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 topikal 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 Standart High Density Polyethline (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	72^0 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
Signature

Institutional Registry No: 2021
Signature

Institutional Registry No: 2486
Signature

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	0.94
Negative Control	0

Signatures of Researchers in Charge of the Test

Institutional Registry No: 975	Institutional Registry No: 2021	Institutional Registry No: 2486
Signature	Signature	Signature

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 neglible 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 TİCARET 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.

Signatures of Researchers in Charge of the Test

Institutional Registry No: 975	**Institutional Registry No: 2021**	**Institutional Registry No: 2486**
Signature	**Signature**	**Signature**

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 Koraltı 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 ☒ Archieved
	Not received ☐

Figure 1: Images of the product

Signatures of Researchers in Charge of the Test

Institutional Registry No: 975	**Institutional Registry No: 2021**	**Institutional Registry No: 2486**
Signature	**Signature**	**Signature**

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
Signature

Institutional Registry No: 2021
Signature

Institutional Registry No: 2486
Signature

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 İrritation 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.

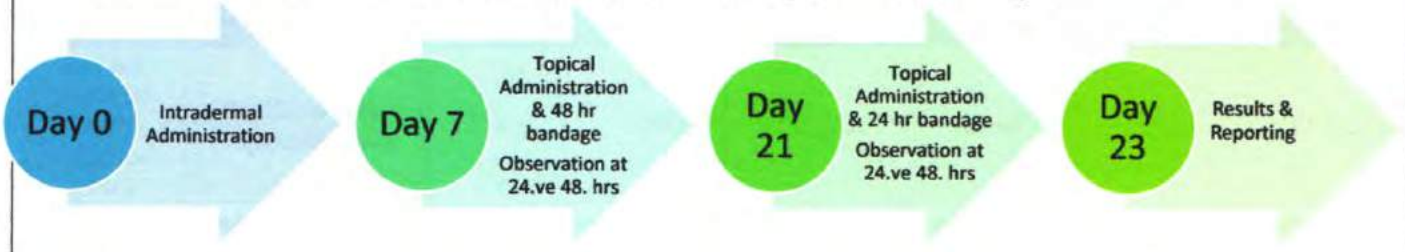
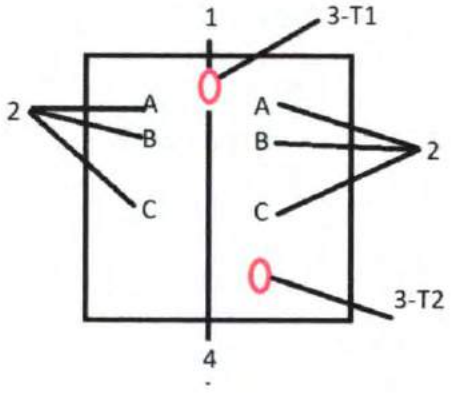


Figure 2: Sensitization Test Plan



1- Cranial End

2- Intradermal Injection Sites

3- Topical Administration Sites

4- Caudal End

Figure 3: Sequence of administration sites in the Sensitization Test

Signatures of Researchers in Charge of the Test

Institutional Registry No: 975	**Institutional Registry No: 2021**	**Institutional Registry No: 2486**
Signature	**Signature**	**Signature**

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	72^0 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 **b)** Test extract **c)** Freund's Adjuvant Complete (FCA) + Test extract solution mixture prepared at 1:1 ratio	**a)** Freund's Adjuvant Complete (FCA) + Saline solution mixture prepared at 1:1 ratio **b)** Saline **c)** Negative Control + Freund's Adjuvant Complete (FCA) solution mixture prepared at 1:1 ratio

Signatures of Researchers in Charge of the Test

Institutional Registry No: 975
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Institutional Registry No: 2021
Signature

Institutional Registry No: 2486
Signature

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) – Chalenge 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

Signatures of Researchers in Charge of the Test

Institutional Registry No: 975
Signature

Institutional Registry No: 2021
Signature

Institutional Registry No: 2486
Signature

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	-	-	-	-	-

Signatures of Researchers in Charge of the Test

Institutional Registry No: 975
Signature

Institutional Registry No: 2021
Signature

Institutional Registry No: 2486
Signature

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.**

Signatures of Researchers in Charge of the Test

Institutional Registry No: 975
Signature

Institutional Registry No: 2021
Signature

Institutional Registry No: 2486
Signature

EUROLAB Laboratory Services

TEST / INSPECTION REPORT

EUROLAB LABORATORY SERVICES

TÜRCERT TEKNİK KONTROL VE BELGELENDİRME A.Ş.

UNITED ACCREDITATION FOUNDATION UAF

5190243IB02

2020170631

Report No:	2020170631
Applicant:	**MY TİCARET VE MEDİKAL A.Ş.** Ömerli mah. General Şükrü Koraltı 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
Hasan KUTLU

Laboratory Manager
Hava SARIAYDIN

Merkez Mh, Gençosman Cd, No 11 / A GÜNGÖREN / İSTANBUL
Tel: 0212 702 20 10 Fax: 0212 909 21 10
Web: www.laboratuvar.com E-mail: info@laboratuvar.com

EUROLAB ® (TÜRCERT TEKNİK KONTROL VE BELGELENDİRME A.Ş.)

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

Merkez Mh, Gençosman Cd, No 11 / A GÜNGÖREN / İSTANBUL
Tel: 0212 702 20 10 Fax: 0212 909 21 10
Web: www.laboratuvar.com E-mail: info@laboratuvar.com

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

Merkez Mh, Gençosman Cd, No 11 / A GÜNGÖREN / İSTANBUL
Tel: 0212 702 20 10 Fax: 0212 909 21 10
Web: www.laboratuvar.com E-mail: info@laboratuvar.com

Tryptic soy broth

Formula/liter:	
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 ± 2) °C for (24 ± 2) h. The culture shall then be diluted in peptone water to give a concentration of approximately 5 × 105 cfu/ml.

The bacterial challenge shall be maintained at (2 200 ± 500) cfu per test. The bacterial challenge shall be determined on the basis of experience and previous positive control plates (see B.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 ± 0,3) µm (see B.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 28,3 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 ± 2) °C for (48 ± 4) h.

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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;

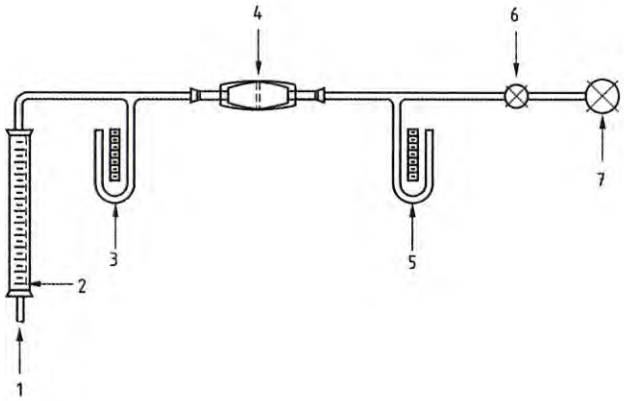
C is the mean of the total plate counts for the two positive control runs;

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

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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:

$$\Delta P = (Xm1 - Xm2)/4,9$$

Where;

Xm1 is pressure in Pa, manometer M1, mean of 5 test areas, low pressure side of the material;
Xm2 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.

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TEST REQUIREMENTS

Test	Type I[a]	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm2)	< 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.

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TEST RESULTS

EN 14683 Inspection

SAMPLE : SURGICAL MASK

Test	Type			Result		Evaluation
Bacterial filtration efficiency (BFE), (%)	1 ≥ 95	2 ≥98	3 ≥98	98,86 99,01 98,92 99,03 99,04	**98.97**	PASS
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

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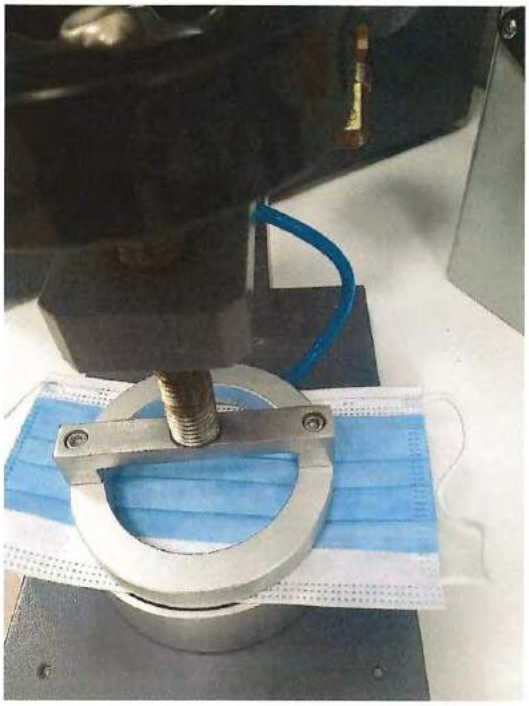
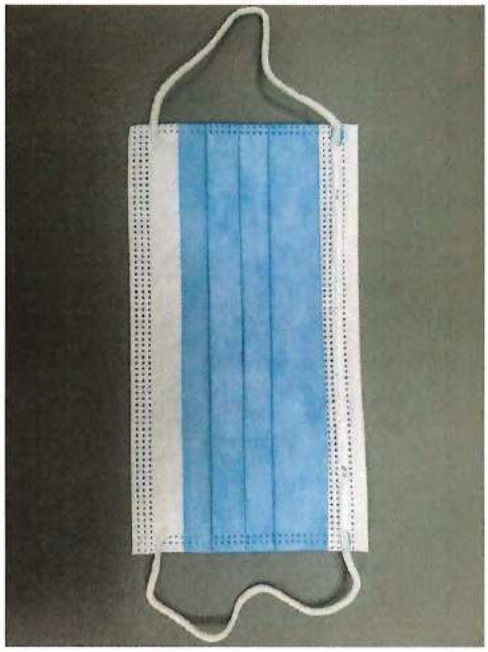
MASK IMAGES UNDER TEST





End of Report

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

TEST REPORT
DENEY RAPORU

Test
TS EN ISO/IEC 17025
AB-0583-T

AB-0583-T
20018616
06-20

Customer name:	MY TİCARET VE MEDİKAL A.Ş.
Address:	Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 ARNAVUTKÖY/ İSTANBUL
Buyer name:	-
Contact Person:	Z.MELEK ÖZ BOLAT
Order No:	-
Article No:	-
Name and identity of test item:	Beyaz elastik kordon.
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

Türk Akreditasyon Kurumu (TÜRKAK) deney raporlarının tanınması konusunda Avrupa Akreditasyon Birliği (EA) ve Uluslararası Laboratuvar Akreditasyon Birliği (ILAC) ile karşılıklı tanınma antlaşmasını imzalamıştır.
Deney laboratuvarı olarak faaliyet gösteren EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş. TÜRKAK'tan AB-0583-T akreditasyon dosya numarası ile ISO 17025:2017 standardına göre akredite edilmiştir.
Deney ve/ veya ölçüm sonuçları, genişletilmiş ölçüm belirsizlikleri (olması halinde) ve deney metodları bu sertifikanın tamamlayıcı kısmı olan takip eden sayfalarda verilmiştir.

Seal	*Date*	*Customer Representative*	*Head of Testing Laboratory*
TESTED BY EKOTEKS TEST EDİLMİŞTİR	18.06.2020	Özlem ULUÇ	Sevim A. RAZAK

EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.

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İSTENEN TESTLER	SONUÇ	AÇIKLAMA
FİZİKSEL ÖZELLİK TESTLERİ		
Malzeme Tayini	-	
İstenen değerler müşteri tarafından belirtilmemiştir.		

NOT: Aksi belirtilmediği taktirde testler ile ilgili kayıtlar 5 yıl, orjinal numuneler 3 ay saklanır. Müşteri tarafından talep edildiğinde, testlere ait ölçüm belirsizliği raporlanır fakat "Geçer/Kalır" değerlendirmesinde ölçüm belirsizliği değeri dikkate alınmaz. Raporlanan belirsizlik, genişletilmiş belirsizlik olup standart belirsizlik kapsam faktörü k=2 kullanılarak elde edilmiştir. Güvenilirlik düzeyi % 95'tir. Bu raporda (*) işaretli deneyler akreditasyon kapsamına dahil değildir.

İmzasız ve mühürsüz raporlar geçersizdir.

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TEST SONUÇLARI

MALZEME TAYİNİ: EKOTEKS 40
FT-IR. Spektrometre test cihazı.

SONUÇ	**İSTENEN**
Poliüretan	-

Not: Bu test sonucu FT-IR spektrometre yöntemi ile Poliüretan referans malzemesi ile karşılaştırılarak tespit edilmiştir. Referans test numunesine benzerliği % 73 bulunmuştur.

Not: Lateks içermemektedir.

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İstanbul/ TÜRKİYE

Test
TS EN ISO/IEC 17025
AB-0583-T

TEST REPORT
DENEY RAPORU

AB-0583-T
20018616-ing
06-20

Customer name:	MY TİCARET VE MEDİKAL A.Ş.
Address:	Ömerli Mahallesi General Şükrü Koraltı 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 (TURKAK) 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.

TESTED BY Seal EKOTEKS TESTE EDİLMİŞTİR

Date	*Customer Representative*	*Head of Testing Laboratory*
18.06.2020	Özlem ULUS	Sevim A. RAZAK

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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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TEST RESULTS

DETERMINATION OF MATERIAL: EKOTEKS 40
FT-IR. Spectrophotometer Test Machine.

RESULT	REQUIREMENT
Polyurethane	-

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.