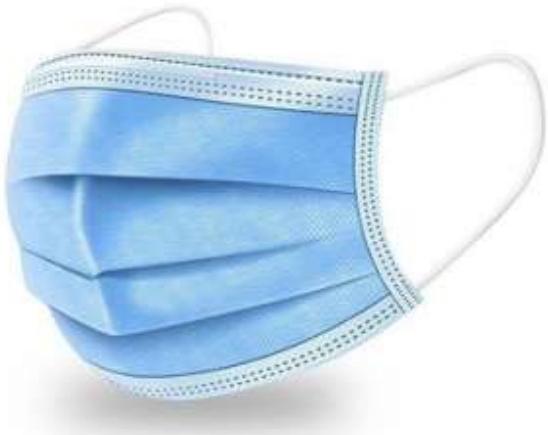


FICHA TÉCNICA Y
DOCUMENTACIÓN

MASCARILLA QUIRÚRGICA IIR

FÁBRICA
MY TICARET VE MEDIKAL A.S

FARMAinca

NOMBRE DEL PRODUCTO:

Mascarilla quirúrgica tipo IIR.

BASIC UDI DI- 868227994MSKXT

Tamaño adulto e infantil.
Desechable.
De un solo uso.
Exentas de látex.
No Estéril.

DISTRIBUIDOR:

INCA PRODUCT S.L.
B-05115159
Calle Reyes Católicos, 8 2ºB
05001 Ávila
info@incaproduct.com
Telf.: 920269774

FABRICANTE:

MY TICARET VE MEDIKAL A.S
Ömerli Mahallesi General Sükrü Koralti
Caddesi nº 33 Arnavutköy
Istanbul (Turkey)

CERTIFICACIONES y DOCUMENTACIÓN ADJUNTA:

-Declaración de conformidad UE conforme Reglamento de producto sanitario 2017/745 y estándar EN 14683:2019+AC:2019

-Certificado de gestión de calidad de productos sanitario, ISO 13485:2016

- Certificado de gestión de calidad, ISO 9001:2015+AC

-Test report emitido por EKOTEKS.

-Ficha técnica My Medikal, con la siguiente documentación:

Información general de la mascarilla
Parametros de estándar EN 14683:2019+AC:2019
Test report de irritabilidad ISO 10993-10
Test report de sensibilidad ISO 10993-10
Test / inspection report por EROLAB LABORATORY SERVICES.
Ekoteks

FARMAinca

TECHNICAL SHEET

Prepared for:

INCA PRODUCTS S.L.
C/Reyes Católicos, 8. 2º B
05001 Ávila España
Tel (+34) 616 79 40 13

Manufacturer:

My Ticaret ve Medikal A.Ş.
Ömerli Mah. General Şükrü Koraltı Cad.
No:33 Arnavutköy, İstanbul

Brand: INCA

Description: Non-sterile, Surgical Mask Type IIR (Adult and Kids)

DEFINITION : INCA 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.

QUALITY SYSTEM OF MY TICARET VE MEDIKAL :

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

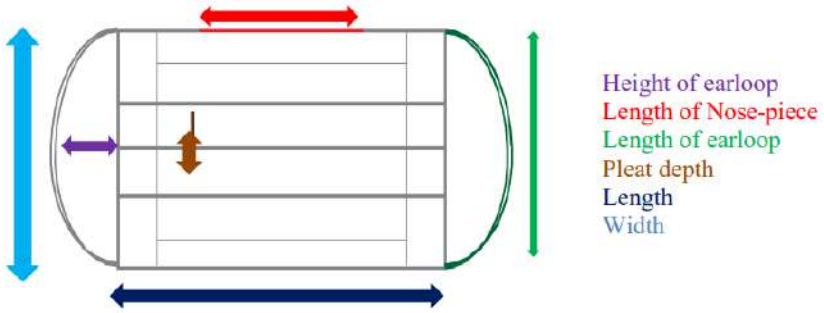
- EN ISO 13485:2016 Quality Assurance System-Medical Devices
- EN ISO 9001:2015+AC Quality Assurance System

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.

SHELF LIFE : 5 Years

DIMENSION

- Adult Surgical Mask



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

- Kids Masks

Dimension (Infant)	**Body Size**	**Length (+/-1 cm)**	145 mm
		Width (+/-1 cm)	95 mm
	Height of Earloop		70 mm
	Length of Earloop		160 mm
	Pleat Depth		10 mm
	Length of Nose-piece		60 mm

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

Reference/Catalog No. and Barcodes

Description	Quantity /box	Catalog #	Inner Box EAN Barcode	Inner box UDI Barcode
Adult Masks, Surgical Type IIR (Black)	50pcs	MM.NS.LM.510	8683020020603	(01)08683020020603(11)MMYY(10)XXXXXXXX
Adult Masks, Surgical Type IIR (Blue)	10pcs	MM.NS.LM.511	8683020020610	(01)08683020020610(11)MMYY(10)XXXXXXXX
Kids Mask, Surgical Type IIR (Blue)	50pcs	MM.NS.LM.512	8683020020627	(01)08683020020627(11)MMYY(10)XXXXXXXX
Kids Mask, Surgical Type IIR (Blue)	10pcs	MM.NS.LM.513	8683020020634	(01)08683020020634(11)MMYY(10)XXXXXXXX
Adult Masks, Surgical Type IIR (Blue)	50pcs	MM.NS.LM.514	8683020020641	(01)08683020020641(11)MMYY(10)XXXXXXXX
Kids Mask, Surgical Type IIR (Pink)	10pcs	MM.NS.LM.558	8683020020665	(01)08683020020665(11)MMYY(10)XXXXXXXX
Kids Mask, Surgical Type IIR (Black)	10pcs	MM.NS.LM.559	8683020020672	(01)08683020020672(11)MMYY(10)XXXXXXXX
Kids Mask, Surgical Type IIR (Octopus Printed)	10pcs	MM.NS.LM.560	8683020020689	(01)08683020020689(11)MMYY(10)XXXXXXXX
Kids Mask, Surgical Type IIR (Panda Printed)	10pcs	MM.NS.LM.561	8683020020696	(01)08683020020696(11)MMYY(10)XXXXXXXX

MY TİCARET VE MEDİKAL A.Ş.
Ömerli Mah. General Şükrü Koraltı Cad. No:33 Arnavutköy / İstanbul
Tel: 0212 438 20 64 Fax: 0212 438 20 65
info@mymedikal.com.tr www.mymedikal.com.tr

MY Medikal

Loading Information (Mega Truck)

Brand	Description	Pcs per box	No. of box per carton	No. of carton per pallet	Max Qty (ctn)	Quantity (boxes)
INCA	Adult Masks, Surgical Type IIR	50pcs	60	16	660	39,600
INCA	Adult Masks, Surgical Type IIR	10pcs	210	16	660	138,600
INCA	Kids Mask, Surgical Type IIR	50pcs	60	20	770	46,200
INCA	Kids Mask, Surgical Type IIR	10pcs	180	20	770	138,600

Description	Pcs per box	No. of box per carton	Inner box Dimension	Outer carton Dimension
Adult Masks, Surgical Type IIR	50pcs	60	18,5cm * 10cm * 10,5cm	60cm * 40cm * 56cm
Adult Masks, Surgical Type IIR	10pcs	210	10.5cm * 20.0cm * 2.68cm	60cm * 40cm * 56cm
Kids Mask, Surgical Type IIR	50pcs	60	15,4cm * 10cm * 10,4cm	60cm * 33cm * 56cm
Kids Mask, Surgical Type IIR	10pcs	180	10,5cm * 17cm * 2,925cm	60cm * 33cm * 56cm

Remarks: Maximum quantity refers to unpalletized goods and loaded to a mega truck.
Mega Truck dimension: 240cm – width x 280cm – height x 1360cm – length

For loading with pallets, information:

Pallet Dimension for adult masks (cm): 80*120*240
Pallet Dimension for kids masks (cm): 100*120*240
Pallet Weight (without masks): 13 kgs
No. of Pallets per Truck(for adult masks): 33
No. of Pallets per Truck(for kids masks): 26

MY TİCARET VE MEDİKAL A.Ş.
Ömerli Mah. General Şükrü Koraltı Cad. No:33 Arnavutköy / İstanbul
Tel: 0212 438 20 64 Fax: 0212 438 20 65
info@mymedikal.com.tr www.mymedikal.com.tr

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 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 MASK, FILTERING HALF/PROTECTIVE FACE MASK, STERILE & NON-STERILE GAUZE SWABS/ LAP SPONGES/ COTTON PADS/ GAUZE, STERILE SYRINGE/NEEDLE

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, STERİL & NON-STERİL GAZ KOMPRES/BATIN KOMPRES/PAMUKLU PED/GAZLI BEZ, STERİL ŞIRINGA/İĞNE ÜRETİMİ VE SATIŞI

ISO 01 940 1179	Jun. 2, 2021	Jun. 4, 2022
Certificate No.	*Date of this Certificate*	*Certification Expiry Date*
Apr. 5, 2021	Jun. 5, 2020	
Date of Audit	*Date of Registration*	*Managing Director / Director*

MDC MEDICERT CERTIFICATE

Medicert Uluslararası Ürün Ve Sistem Belgelendirme Ltd. Şti.
Tersane Mah. Cemal Gürsel Cad. No:11/3 Halide Hnm. Apt. Karşıyaka / İzmir
Tel: 0232 327 33 44 www.medicert.com.tr info@medicert.com.tr

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

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	Mar. 8, 2021	Feb. 25, 2022
Certificate No.	*Date of this Certificate*	*Certification Expiry Date*
Feb. 8, 2021	Feb. 26, 2020	
Date of Audit	*Date of Registration*	*Managing Director / Director*

MDC MEDICERT CERTIFICATE

Medicert Uluslararası Ürün Ve Sistem Belgelendirme Ltd. Şti.
Tersane Mah. Cemal Gürsel Cad. No:11/3 Halide Hnm. Apt. Karşıyaka / İzmir
Tel: 0232 327 33 44 www.medicert.com.tr info@medicert.com.tr

DECLARATION OF CONFORMITY TO
MEDICAL DEVICE REGULATION 2017/745

Manufacturer : My Ticaret ve Medikal A.Ş

Manufacturer's Address : Ömerli Mahallesi General Şükrü Koraltı Caddesi No: 33 Arnavutköy/İstanbul/Turkey

This declaration of conformity covers the Class 1 medical device products mentioned below.

Device Description:

Brand	Device Name	Catalog /Ref No
INCA	Non Sterile Adult Surgical Masks, 3 Ply Type IIR (Black) 50 pcs	MM.NS.LM.510
INCA	Non Sterile Adult Surgical Masks, 3 Ply Type IIR (Blue) 10 pcs	MM.NS.LM.511
INCA	Non-Sterile Kids Surgical Mask, 3 Ply Type IIR (Blue) 50 pcs	MM.NS.LM.512
INCA	Non- Sterile Kids Surgical Mask, 3 Ply Type IIR (Blue) 10 pcs	MM.NS.LM.513
INCA	Non-sterile Adult Surgical Masks, 3 Ply Type IIR (Blue) 50 pcs	MM.NS.LM.514
INCA	Non-sterile Kids Surgical Mask, 3 Ply Type IIR (Pink) 10 pcs	MM.NS.LM.558
INCA	Non-sterile Kids Surgical Mask, 3 Ply Type IIR (Black) 10 pcs	MM.NS.LM.559
INCA	Non-sterile Kids Surgical Mask, 3 Ply Type IIR (Octopus Printed) 10 pcs	MM.NS.LM.560
INCA	Non-sterile Kids Surgical Mask, 3 Ply Type IIR (Panda Printed) 10 pcs	MM.NS.LM.561

A surgical mask, also known as a medical face mask, is a personal protective equipment worn by healthcare professionals during medical procedures. It is a medical device that, when properly fitted, prevents the transmission of airborne infections between patients and/or treatment personnel by preventing pathogens (primarily bacteria and viruses) emitted in respiratory droplets and aerosols from entering the user's mouth and nose.

Device Classification : Medical Device Class I, according to MD Regulation (EU)2017/745.

Conformity Assesment Procedure : Annex II&III Medical Device Regulation (EU)2017/745

MDR Conformity Route: : Self Declaration

Basic UDI-DI : 868302002MSKMH

MY TICARET VE MEDIKAL A.Ş
Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 Arnavutköy/İstanbul/Turkey

We, My Ticaret ve Medikal A.Ş. herewith declared that above mentioned device:

- İs in conformity with The Regulation (EU) 2017/745 of The European Parliament and of The Council of medical devices.

This EU declaration of conformity is issued under the sole responsibility of the manufacturer, My Ticaret ve Medikal A.Ş.

Applied standards: EN 14683:2019+AC:2019

Verification Certificates Authorized Signatory : Quality Management System EN 13485:2016

EU DoC Issuance date : 30.11.2021

Signed For and Behalf of My Ticaret ve Medikal A.Ş.

Name: MURAT YILDIZ

Designation: General Manager

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

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

TEST REPORT
DENEY RAPORU

AB-0583-T
20031582-ing
09-20

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:	SAMPLE 1
Article No:	MM.NS.LM.01 MUMU SURGICAL MASK
Name and identity of test item:	Blue non-woven mask.
The date of receipt of test item:	01.09.2020
Re-submitted/re-confirmation date:	-
Date of test:	01.09.2020-10.09.2020
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:	5

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.

Seal	***Date***	***Customer Representative***	***Head of Testing Laboratory***
	11.09.2020	Özlem ULUS	Sevim A. RAZAK 11.09.2020

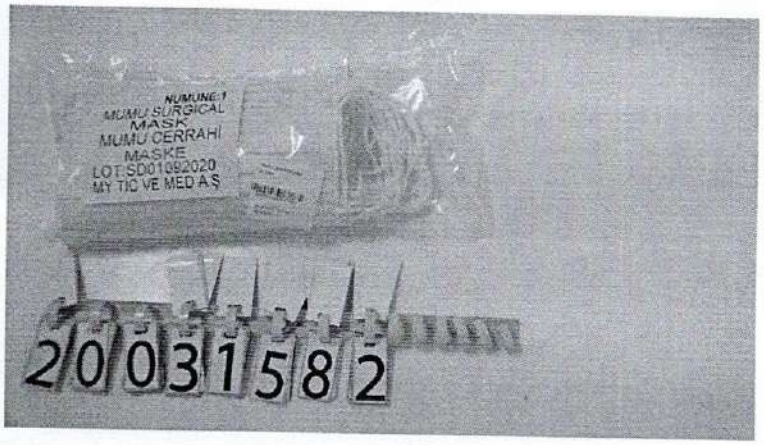
Gen.f136-2/03

AB-0583-T
20031582-ing
09-20

REQUIRED TESTS	RESULT	COMMENTS
MICROBIOLOGICAL TESTS		
Bacterial Filtration Efficiency-BFE	P	TYPE IIR
Microbial Cleanliness(Bioburden)	P	
Splash Resistance	P	
PHYSICAL PROPERTIES		
Breathability(Differential Pressure)	P	

P: Pass
F: Fail
R: Refer to retailer technologist.
Tests results were evaluated according to EN 14683:2019+AC :2019 Tablo 1 limit values.

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.



AB-0583-T
20031582-ing
09-20

TEST RESULTS

BACTERIAL FILTRATION EFFICIENCY (BFE)

Test Metod: (Bacterial Filtration Efficiency Testing –BFE /Ref: EN 14683:2019+AC:2019 Medical Face Masks,Requirements and Test Methods

A specimen of the mask material is clamped between a 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.

Test Flow Rate	28,3 L/min
Test Flow Time	2 minute
Sample Sizes	5 pieces mask
Microorganism	*Staphylococcus aureus* ATCC 6538
Bacterial concentration (cfu/ ml)	$5x10^5$ cfu/ ml
incubation conditions	24 hour, 35°C ± 2°C
Positive control sample average of number of Bacteria (C)	**$1,93 x10^3$ cfu/ ml**

RESULTS			
Number of Test Sample	**Test Sample (T) Number of Bacteria (cfu/ml)**	**Bacterial Filtration Efficiency (% B)**	**Requirement BFE (%)**
1	38	98,0%	**Type I ≥95** **Type II ≥98**
2	33	98,3%	
3	29	98,5%	
4	24	98,8%	
5	31	98,4%	

cfu: Colony-forming unit

B= (C-T) / C x 100

%B: Bacterial Filtration Efficiency
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

AB-0583-T
20031582-ing
09-20

TEST RESULTS

MICROBIAL CLEANLINESS (Bioburden)

Test Metod: EN ISO 11737-1:2018

The sample is put in extraciton liquid after shaking well, inoculated on the agar.
After incubation at 30 ± 1 ° C for 72 hours, growth microorganisms are counted on the agar.

	RESULTS	REQUIREMENT
Microbial cleanliness (cfu/g)	16 cfu/g	≤30 cfu/g

***cfu= Colony forming unit.**

SPLASH RESİSTANCE

Test Metod: EN 14683:2019+AC :2019 (Clause 5.2.4) 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

ISO 22609 :2004 Clothing for protection against infectious agents — Medical face masks — Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)

Test Condition (21 ± 5) °C ve (85 ± 5) % relative humidity, 4 hrs

6 different samples were taken

	SPLASH RESISTANCE PRESSURE (kPa)	RESULTS	REQUIREMENT
1	>21.3 kPa	**PASS**	≥16 kPa
2	>21.3 kPa	**PASS**	
3	>21.3 kPa	**PASS**	
4	>21.3 kPa	**PASS**	
5	>21.3 kPa	**PASS**	
6	>21.3 kPa	**PASS**	
Average Result	>21.3 kPa	**PASS**	

AB-0583-T
20031582-ing
09-20

TEST SONUÇLARI

BREATHABILITY (Differential Pressure)

Test Method: EN 14683:2019+AC :2019 (TS EN 14683+AC:2019) Annex-C

Test Condition (21 ± 5) °C ve (85 ± 5) % relative humidity, 4 hrs
Test area is 25 mm in diameter , 5 different sample was taken
Adjusted airflow is 8 l/min.The differential pressure is read directly using a differential pressure manometer .

SAMPLE	DIFFERENTIAL PRESSURE RESULT	REQUIREMENT
1	24.3 Pa/cm^2	< 60 Pa/cm^2
2	23,1 Pa/cm^2	
3	24,8 Pa/cm^2	
4	29,0 Pa/cm^2	
5	22,7 Pa/cm^2	
Average Result	24,7 Pa/cm^2	

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

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

TEST REPORT
DENEY RAPORU

AB-0583-T
21034818
12-21

Customer name:	MY TİCARET VE MEDİKAL A.Ş.
Address:	Ömerli Mahallesi General Şükrü Koraltı Caddesi No:33 ARNAVUTKÖY/ İSTANBUL
Buyer name:	-
Contact Person:	HİLAL YİĞİT
Order No:	-
Article No:	Surgical Kids Mask / MM.NS.LM.29
Name and identity of test item:	Printed white non-woven medical mask
The date of receipt of test item:	17.11.2021
Re-submitted/re-confirmation date:	24.11.2021
Date of test:	24.11.2021-02.12.2021
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.

Seal	***Date***	***Customer Representative***	***Head of Testing Laboratory***
TESTED BY EKOTEKS TESTEDİLMİŞTİR	02.12.2021	Özlem ULUS	Sevim A. RAZAK 02.12.2021

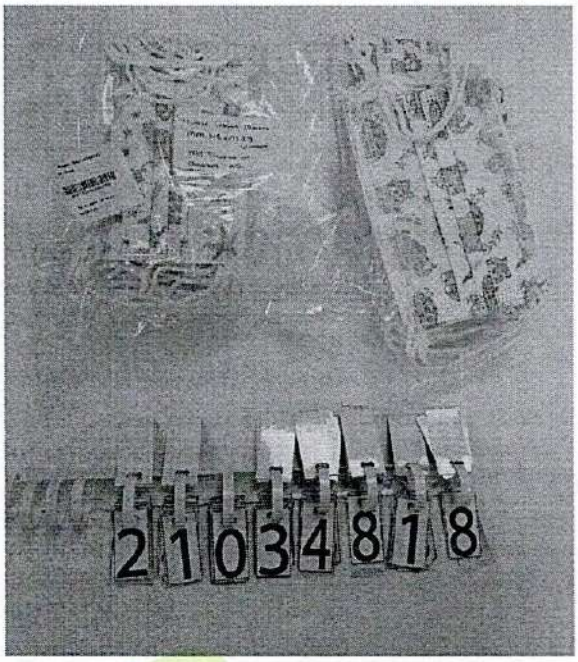
EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.

AB-0583-T
21034818
12-21

REQUIRED TESTS	EVALUATION	COMMENTS
MICROBIOLOGICAL TESTS		
Bacterial Filtration Efficiency-BFE	P	

P: Pass
F: Fail
R: Refer to retailer technologist.
Tests results were evaluated according to EN 14683:2019+AC :2019 Tablo 1 limit values.

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 %. The declaration of conformity was given in accordance with the Simple Acceptance Decision Rule. Tests marked (*) in this report are not included in the accreditation schedule.



Gen.f136-2/03

Testing reports without signature and seal are not valid.

AB-0583-T
21034818
12-21

TEST RESULTS

BACTERIAL FILTRATION EFFICIENCY (BFE)

Test Metod: (Bacterial Filtration Efficiency Testing –BFE /Ref: EN 14683:2019+AC:2019 Medical Face Masks,Requirements and Test Methods

A specimen of the mask material is clamped between a 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.

Test Flow Rate	28,3 L/min
Test Flow Time	2 minute
Sample Sizes	5 pieces mask
Microorganism	*Staphylococcus aureus* ATCC 6538
Bacterial concentration (cfu/ ml)	$5x10^5$ cfu/ ml
incubation conditions	24 hour, 35°C ± 2°C
Positive control sample average of number of Bacteria (C)	**$3,0 x10^3$ cfu/ ml**

RESULTS			
Number of Test Sample	**Test Sample (T) Number of Bacteria (cfu/ml)**	**Bacterial Filtration Efficiency (% B)**	**Requirement BFE (%)**
1	42	98,6%	**Type I ≥95** **Type II ≥98**
2	44	98,5%	
3	43	98,6%	
4	45	98,5%	
5	48	98,4%	

cfu: Colony-forming unit

B= (C-T) / C x 100

%B: Bacterial Filtration Efficiency
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

Total Uncertainty: 0,40

EUROLAB®
Laboratory Services

TEST/MUAYENE RAPORU

EUROLAB LABORATUVAR HİZMETLERİ

TÜRCERT TEKNİK KONTROL VE BELGELENDİRME A.Ş.

UNITED ACCREDITATION FOUNDATION UAF

5190243IB02

2020080611

Test Result : **PASS / Level 2**

Report No : 2020080611
Applicant: **MY TİCARET VE MEDİKAL A.Ş.**
Ömerli mah. General Şükrü Karaltı cad. No:33 Arnavutköy/ İstanbul
Contact Person : Z. Melek ÖZ BOLAT
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Sample Accepted on: 10.07.2020
Report Date: 06.08.2020
Total number of pages: 5 (syf)
Sample ID: **Surgical Mask 3-Ply With Earloop**

	TEST	METHOD	RESULTS
*	Standard Specification for Performance of Materials Used in Medical Facial Masks	ASTM F 2100	PASS
*	Standard Test Method for Determining the First Efficiency of Substances Used in Medical Facial Masks to Penetration Using Particles Using Latex Spheres	ASTM F 2299	PASS

TÜRCERT TEKNİK KONTROL VE BELGELENDİRME A.Ş. TÜRCERT

Seal

Customer Representative
Hasan KUTLU

EUROLAB LABORATUVAR HİZMETLERİ TÜRCERT

Laboratory Manager
Hava Sarıaydın

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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

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ASTM F 2100 : Standard Specification for Performance of Materials Used in Medical Facial Masks

This specification covers tests and requirements for the materials used in making medical face masks used in the provision of health services such as surgery and patient care.

This specification provides a classification of medical face mask material performance. Medical face mask material performance is based on bacterial filtration efficiency, differential pressure, submicron particle filtration efficiency, resistance to synthetic blood penetration and flammability tests.

Necessity :

Characteristic	Level 1	Level 2	Level 3
Bacterial Filtration Efficiency (%)	% 95	% 98	% 98
Differential Pressure mm H_2O / cm^2	< 4,0	< 5,0	< 5,0
Submicron Particle Filtration Efficiency 0.1 micron (%)	% 95	% 98	% 98
Synthetic Blood Penetration Resistance (min.pressure in mmHg)	80	120	160
Combustion Class	Class 1	Class 1	Class 1

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ASTM F 2299 : Standard Test Method for Determining the First Efficiency of Substances Used in Medical Facial Masks to Penetration Using Particles Using Latex Spheres

This test method creates procedures to measure the initial particle filtration efficiency of materials used in medical face masks using monodispers aerosols. This test method uses luminous particle counts from 0.1 to 5.0 µm in size and air flow test speeds of 0.5 to 25 cm / s.
The test procedure measures the filtration efficiency by comparing the number of particles in the feed stream (upstream) with the filtrate (downstream).

Test Results

Tests	Results			
	1	2	3	Avg
Liquid Resistance, mmHg	116	116	116	116
BFE	% 98,85	% 98,82	% 98,91	% 98,86
PFE, 0.1 micron %	% 98,01	% 98,06	% 98,04	%98,03
Differential Pressure, mm H_20 / cm^2	2,3	2,2	2,2	2,23
Combustion Class	Class 1 Flare up	Class 1 Flare up	Class 1 Flare up	Class 1 Flare up

Comment : Results meet Level 2 criteria

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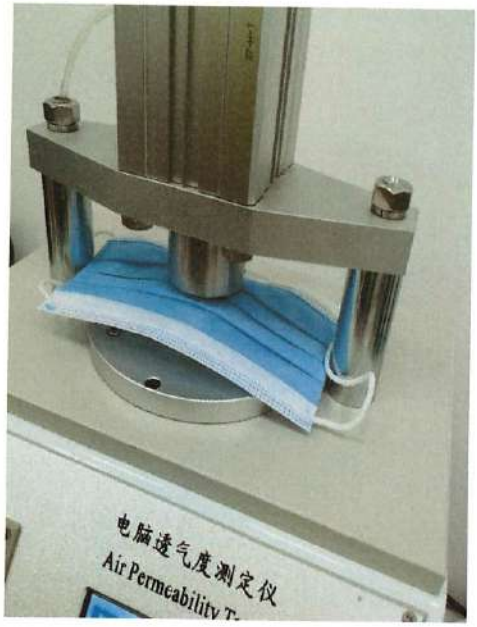
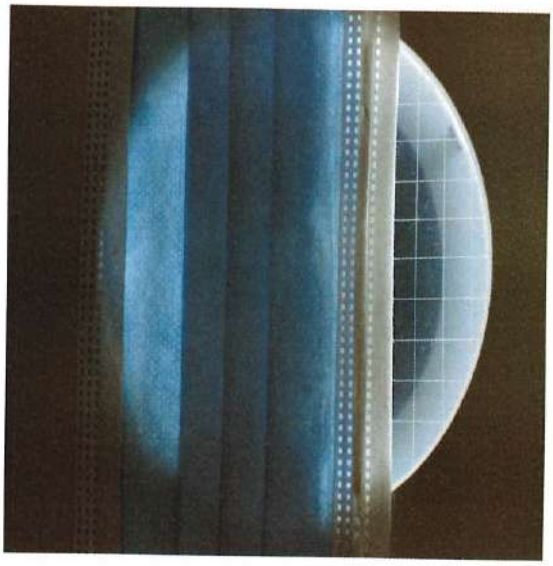
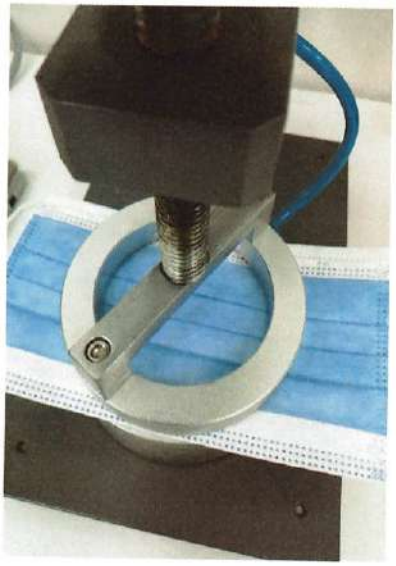
Images Under Test







End of Report

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PACKING METHOD

Ref No. MM.NS.LM.512

Ref No. MM.NS.LM.510

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Ref No. MM.NS.LM.513

Master carton

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