Technical Universal Verification

CERTIFICATE

This Certificate has been awarded to:

YILDIRIM LED VE SES TEKNOLOJİLERİ SAN. TİC. LTD. ŞTİ

FENER MAH. BÜLENT ECEVİT BLV. NO:48 MURATPAŞA

ANTALYA - TURKEY

In Recognition of the Organisation's Management System which complies with:

ISO 13485 : 2016

For the Scope of Activities described below:

PRODUCTION, SALES AND EXPORT OF DISPOSABLE 3-LAYER WIRED/WIRELESS MASK, FFP2 MASK

Certificate No : 4203

Date of Audit : 02.04.2021

Date of Registration : 18.05.2021

Reissue Date : -

Expiry Date : 17.05.2022

Technical Universal Verification

This document is valid for 3 years provided that the management system is well maintained and surveillance audits are performed regularly.
After performing the surveillance audits certificate will be reissued. The current status of this certificate can be viewed via www.techcert.com.tr web site.
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Technical Universal Verification Belgelendirme Laboratuvar
Eğitim ve Sağlık San.ve Tic.Hizmetleri Ltd. Şti.
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NAC

MANAGEMENT SYSTEM
ISO/IEC 17021-1:2015
NAC-011-MS

Technical Universal Verification

CERTIFICATE

OF ATTESTION FOR TECHNICAL FILING FOR

Üreticinin Ticari Ünvanı & Legal Entitty : YILDIRIM LED VE SES TEKNOLOJİLERİ SAN. TİC. LTD. ŞTİ.

Adres & Adresss : FENER MAH. BÜLENT ECEVİT BLV. NO: 48 MURATPAŞA - ANTALYA - TÜRKİYE

Listelenen ürünlerine ait üretim yerlerini, kritik tedarikçilerini, yapım özelliklerini ve uygulanabilir teknik düzenleme standartlara ait raporları da içeren teknik dosyaları incelenmiş, Covering production place, critical suppliers, construction specifications and reports regarding applicable technical regulations and standards of below its listed products has been reviewed and concluded that it fulfills the requirements of;

93/42/EEC Tıbbi Cihazlar Yönetmeligi Sınıf I, Kural 1 & 93/42/EEC Medical Devices Directive Class I, Rule 1

AT Direktifleri şartlarını karşıladığı kanaatine varılmıştır. EU directives it has come to the conclusion that it meets the conditions.

Ürün(ler) & Product(s): Üç Katlı Tıbbi Yüz Maskesi (Tek Kullanımlık) - TIP 1, TIP 2, TIP 2R, FFP2 (Filitresiz)

Three Layer Medical Face Mask (Disposable) - TYPE 1, TYPE 2, TYPE 2R, FFP2 (No Filter)

Technical Documentation Code(s): YLD01 Rev00/ 05.05.2020

Uygulanabilir Standardlar & Applicable Standards: EN 13485:2016, EN 1041:2008, EN ISO 14971 :2012, EN ISO 15223-1:2016, EN 14683:2019, EN ISO 10993-1:2018, EN ISO 10993-5:2009, EN ISO 10993-10:2010, EN ISO 10993-12:2012, EN149+A1:2009

Verilme Tarihi & Date of Issue: 06.05.2021 Geçerlilik Tarihi & Expiry Date: 05.05.2022 Sertifika No & Certificate No: MDD/2021/1222

Revizyon Tarihi & Revision Date: 21.09.2021

Technical Universal Verification

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CE

EU DECLARATION OF CONFORMITY

MANUFACTURER

YILDIRIM LED VE SES TEKNOLOJİLERİ SAN. TİC. LTD. ŞTİ.
Fener Mah. Bülent Ecevit Bulvarı No:48 Muratpaşa ANTALYA / TURKEY

PRODUCT DESCRIPTION

Layered and molded medical device classified in the Class I - Medical Device to be used as protection against inhalation of viruses, bacteria, other microorganisms, allergens from the environment

Brand Name : MASKY
Model : YLD01
Type IIR

The Producer / the Manufacturer declares on his sole responsibility that the product above is, under conditions of normal use and conditions defined by the Producer / the Manufacturer, safe and meets all the necessary legal conditions and requirements. The product, a medical device that is intended for single use and solely in accordance with the Producer's / the Manufacturer's instructions.

The Conformity is assessed especially with the following provisions:

- Government Regulation no. 93/42/EEC Medical devices establishing technical requirements for medical devices, in effective wording
- Technical standard EN 14683:2019+AC:2019 Medical face masks - Requirements and test methods
- Other relevant harmonized legislation
- Other relevant local, national and community standards
- For the assessment of conformity, the following documents were also applied to:
- Tests for irritation and delayed-type hypersensitivity
- Results of laboratory tests Çevre Endüstriyel Testing Laboratory Bavterial filtration efficiency
- Results of laboratory tests Çevre Endüstriyel Testing Laboratory Microbial Cleanliness
- Results of laboratory tests Çevre Endüstriyel Testing Laboratory Differential Pressure
- Results of laboratory tests Çevre Endüstriyel Testing Laboratory Splash Resistance Pressure

MARKİNG, LABELLİNG

Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the medical face mask is supplied. The following information shall be supplied:
type of mask (as indicated in Table 1). EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered

MEASURES TO ENSURE CONFORMITY

The Producer / the Manufacturer declares that he has taken all necessary measures to ensure the conformity of products placed on the market with technical documentation and basic requirements for this type of product.

CE

General Manager
Istanbul 02/09/2020

YILDIRIM LED VE SES TEKNOLOJİLERİ SAN. TİC. LTD. ŞTİ.
Fener Mah. Bülent Ecevit Bulvarı
No: 48 Muratpaşa / ANTALYA
Ant. Kurumlar V.D. 7960 006 9395
Tic. Sic. No:18522
Mersis No: 0-7960-0069-9500018
YILDIRIM

ÇEVRE
ENDÜSTRİYEL ANALİZ
LABORATUVARI

ANALYSIS REPORT

Report No. : **2021067E-R1** Report Date : 31/08/2020

123 : Flow rate during testing : 8 L/dk
124 : Flow rate during testing : 28.3 L/dk
Test performed with the inside of the medical face mask in contact with the bacterial challenge.
126 : The mask analyzed according to the results of Differential Pressure provides EN 14683 Table 1. Type I, Type II and Type IIR limits.
129 : The mask analyzed according to the results of Bacterial Filtration Efficiency (BFE) provides EN 14683 Table 1. Type I,Type II and Type IIR limits.
131 : The mask analyzed according to the results of Microbial Limit - Bioburden provides EN 14683 Table 1. Type I, Type II and Type IIR limits.
133 : The mask analyzed according to the results of Differential Pressure provides EN 14683 Table 1. Type IIR limits.
133 : The mask analyzed according to the results of Differential Pressure provides EN 14683 Table 1. Type IIR limit.
142 : The Splash Resistance Pressure is determined based on the value specified in EN 14683 Table 1. Type IIR.
144 : The test was applied from the inner surface on the mask to the outher surface, as required by the standard.
146 : According to ISO 22609, when 29 or more of the 32 samples tested show "pass" results, an acceptable 4.0% quality limit is met for a single sampling plan. Acceptable 4.0% quality limit is met for normal sampling plan according to analysis results.
147 : Test Parameters : 50,6 relative humidity and 25,4°C

R1 : This report supersedes 31/08/2020 date 2021067E number of report which is invalid.

Note

1. When request, the conformit assessment is carried out in accordance with the legal regulations and standards or the decision rules which are agreed with the customer.
2. Descriptive information about the samples / sampling in the analysis report has been declared by the customer. Our laboratory is not responsible for the legal losses.
3. Analysis report covers samples/sampling that comes to the laboratory.
4. This report and results don't not be copied and printed partially or completely without permission of Cevre Industrial Analysis Laboratory for any commercial and advertising purposes.
5. This report shall not be used official purposes related to Enviromental Regulations.
6. The test report without sign is not valid.

End of Report

Kübra HANCI AKAN
Microbiology Laboratory Responsible

Approved by
31/08/2020
Ömer Yasin BALIK
Laboratory Manager

Çevre Endüstriyel Analiz Laboratuvarı Hiz. Tic. A.Ş. Merkez Mahallesi Tatlıpınar Sokak No:13 Mart Plaza Kat:2/A Kağıthane / İstanbul

ÇEVRE
ENDÜSTRİYEL ANALİZ
LABORATUVARI

ANALYSIS REPORT

Report No. : **2021067E-R1**

Report Date : 31/08/2020

Following analysis results were obtained from the specimen which was delivered by cargo to Çevre Laboratory;

Parameters	Unit	Finding	Tip I	Tip II	Tip IIR	LR Source	Method	Information
Analyzed Mask Surface	-	Outside	-	-	-		-	
Point of Analysis	-	Midpoint	-	-	-	-		
Bacterial Filtration Efficiency								
BFE - 1	%	99,8	≥95	≥98	≥98	97	EN 14683 - Annex B 122, 124, 129	
BFE - 2	%	99,6	≥95	≥98	≥98	97	EN 14683 - Annex B 122, 124, 129	
BFE - 3	%	99,7	≥95	≥98	≥98	97	EN 14683 - Annex B 122, 124, 129	
BFE - 4	%	99,7	≥95	≥98	≥98	97	EN 14683 - Annex B 122, 124, 129	
BFE - 5	%	99,6	≥95	≥98	≥98	97	EN 14683 - Annex B 122, 124, 129	
Mean Positive Control Count	cfu	1873	-	-	-	-	EN 14683 - Annex B	
Negative Control Count	cfu	<1	-	-	-	-	EN 14683 - Annex B	
Mean Particle Size (MPS)	µm	3,2	-	-		-	EN 14683 - Annex B	
Microbial Limit - Bioburden								
Bioburden - 1	cfu/g	<3	≤30	≤30	≤30	97	ISO 11737-1	120, 131
Bioburden - 2	cfu/g	<3	≤30	≤30	≤30	97	ISO 11737-1	120, 131
Bioburden - 3	cfu/g	<3	≤30	≤30	≤30	97	ISO 11737-1	120, 131
Bioburden - 4	cfu/g	<3	≤30	≤30	≤30	97	ISO 11737-1	120, 131
Bioburden - 5	cfu/g	<3	≤30	≤30	≤30	97	ISO 11737-1	120, 131

Source of Limit Ranges : 97 Medikal Yüz Maskelerinin Test Metodları ve Performans Gereksinimleri (EN 14683)

A: Acceptable NA: Not Acceptable

MU: Measurement Uncertainty

Method
ISO : International Organization for Standardization
EN : European Standard
ISO : International Organization for Standardization

Information
120 : Bioburden : Aerobic Bacteria and Mold-Yeast
Pozitive Controls : Bacillus atrophaeus
Extract Fluid : Peptone, Tween with Sodium Chloride
Extract Fluid Volume : 300 mL
Plating Method : Membrane Filtration
Agar Medium : Tryptic Soy Agar for Aerobic Bacteria Count and Sabouraud Dextrose Agar with Chloramphenicol for Mold and Yeast Count
Recovery Efficiency : Repetitive Rinse Method
Aerobic Bacteria : Plates are incubatede 3 days at 30-35°C, then enumerated.
Yeast - Mould : Plates are incubatede 5-7 days at 20-25°C, then enumerated.
122 : Conditioning Parameters : 85± 5 relative humidity and 21± 5 °C de minimum 4 hours

Kübra HANCI AKAN
Microbiology Laboratory Responsible

Approved by
31/08/2020
Ömer Yasin BALIK
Laboratory Manager

Çevre Endüstriyel Analiz Laboratuvarı Hiz. Tic. A.Ş. Merkez Mahallesi Tatlıpınar Sokak No:13 Mart Plaza Kat:2/A Kağıthane / İstanbul
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ÇEVRE
ENDÜSTRİYEL ANALİZ
LABORATUVARI

ANALYSIS REPORT

Report No. : **2021067E-R1**

Report Date : 31/08/2020

Applicant : YILDIRIM LED ve SES TEKNOLOJİLERİ SAN.TİC.LTD.ŞTİ.

Address : Fener Mah. Bülent Ecevit Bulvarı no:48 Muratpaşa Antalya/Turkey

Sample : Full Ultrasonic 3 Layer Nose Wire Rubber Mask - Masky (1)

Sample Package	: Original carton box
Sample Amount	: 50 adet x 2 kutu
Sampling Point	: -
Sampling Date	: -
Sample Lot No.	: -
Sample Carrying Conditions / Preservation Technique	: -
Production Date	: -
Packing Date	: -
Expire Date	: -
Producer Company	: -
Sample Receiving Time	: 18/07/2020 10:45:00
Analysis Beginning Time	: 06/08/2020 11:00:00
Analysis Completion Time	: 31/08/2020

Following analysis results were obtained from the specimen which was delivered by cargo to Çevre Laboratory;

Parameters	Unit	Finding	Tip I	Tip II	Tip IIR	LR Source	Method	Information
Differential Pressure								
DP - 1	Pa/cm²	58,9	< 40	< 40	< 60	97	EN 14683 - Annex C	122, 123, 133, 144
DP - 2	Pa/cm²	34,4	< 40	< 40	< 60	97	EN 14683 - Annex C	122, 123, 126, 144
DP - 3	Pa/cm²	39,5	< 40	< 40	< 60	97	EN 14683 - Annex C	122, 123, 126, 144
DP - 4	Pa/cm²	42,2	< 40	< 40	< 60	97	EN 14683 - Annex C	122, 123, 133, 144
DP - 5	Pa/cm²	49,4	< 40	< 40	< 60	97	EN 14683 - Annex C	122, 123, 133, 144
Splash Resistance Pressure								
Splash Resistance Pressure	kPa	16	-	-	≥16	97	ISO 22609	122, 142, 146, 147
Number of Masks Analyzed	-	32	-	-	-	-	-	
Number of Passed Masks Analyzed	-	32	-	-	-	-	-	

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31/08/2020
Ömer Yasin BALIK
Laboratory Manager

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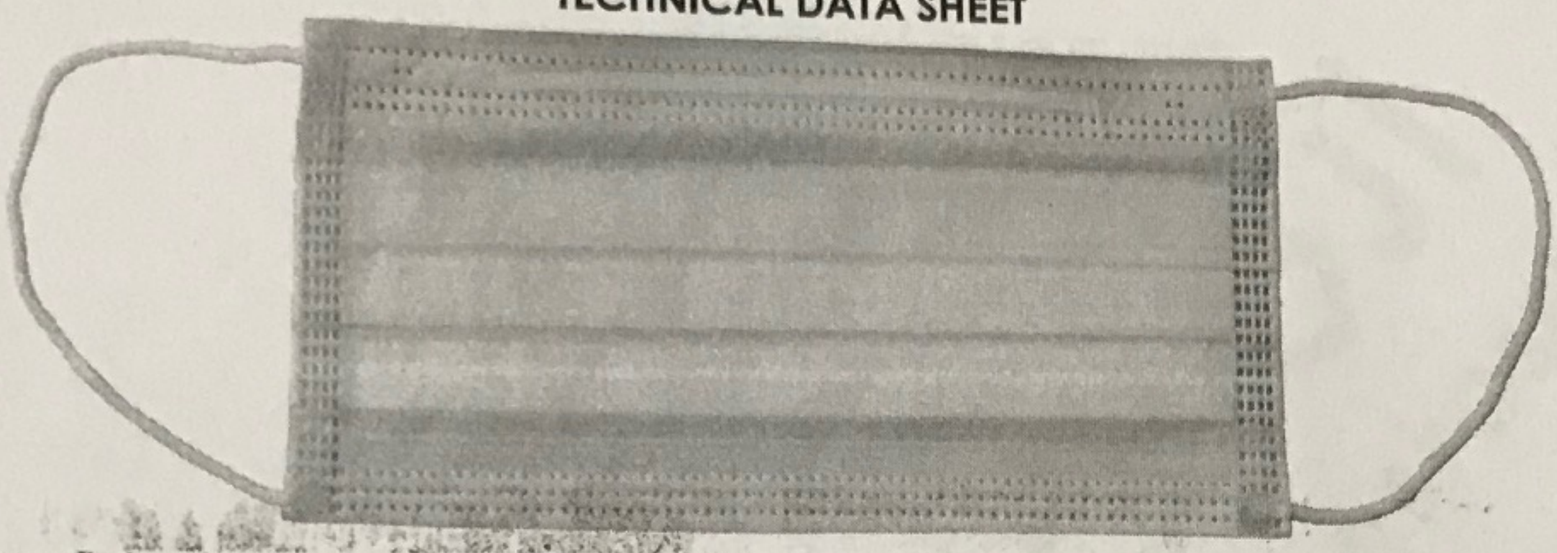
YILDIRIM LED VE SES TEKNOLOJİLERİ SAN. TİC. LTD. ŞTİ.
Tel: +90 850 840 93 55 Mail: info@masky.com.tr
Fener Mah. Bülent Ecevit Bulv. No:48 Muratpaşa/Antalya, Türkiye
www.masky.com.tr

DISPOSABLE FACE MASK
EN14683:2019+AC:2019 TYPE IIR
MODEL: YLD01

TECHNICAL DATA SHEET



- Three layer flat polypropylene mask, folded, 3 layers made of non-woven fabric does not irritate skin

- Breathable, soft and odorless

- Protection for splashes

- Antibacterial filter layer stops microbes and other particles from entering or exiting mask

- Ultra elastic ear-loops specialy made for our mask with great tension

that doesn't cause any strain on ears

- Antibacterial nose clip coated with PVC. Lenght: ~110mm

- Customizable color options

- Made by full ultrasonic machines

- Non Sterile

- Does not contain latex and fiberglass

- Hypoallergenic

- Bacterial Filtration Efficiency: ≥98%

-Single Use

Mask Size: ~17.5*9.5cm

Mask Weight: ~ 2.45 gr (+/- %5)

With closed folds: ~95mm - With open folds: ~175mm

Box: 50pcs in a bag (customizable)

Box Size: 19,7*9,7*10cm

Outer Box Size: 41*50*42 cm(contains 40 inner boxes)

Palette Size: 103*123*266 cm (contains 36 outer boxes)

Polybag: optional

Certificate Number: MDD-245