

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 9001: 2015

For the Scope of Activities described below:

MATERIAL MANUFACTURING, SALES, INSTALLATION AND COMMITMENT WORKS, REPAIR, MAINTENANCE AND TECHNICAL SERVICES FOR SOUND, LIGHT AND VISUAL SYSTEMS, PRODUCTION, SALES AND EXPORT OF DISPOSABLE 3-LAYER WIRED/WIRELESS MASK, FFP2 MASK

Certificate No : 1324 Reissue Date : -

Date of Audit : 01.04.2021 Expiry Date : 17.05.2022

Date of Registration: 18.05.2021

Technical Universal Verification

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Technical Universal Verification Belgelendirme Laboratuvar Eğitim ve Sağlık San.ve Tic.Hizmetleri Ltd. Şti. Macun Mahallesi Batı Bulvarı ATB İş Merkezi A Blok No: 1/3 Yenimahalle - ANKARA / TÜRKİYE Tel.: 00 90 312 231 82 02

- web: www.techcert.com.tr
- e-mail: info@techcert.com.tr



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



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

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



AB Tip İnceleme Sertifikası EU Type-Examination Certificate

Belge No / Certificate No : 151-21-01

Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /

Certification Date / Certificate Validity Date : 09.02.2021-09.02.2026

Belge Geçerlilik Tarihi / Document Validity Period: 5 yıl / 5 years

Firma Unvanı ve Adresi /

Company Name and Address : YILDIRIM LED VE SES TEKNOLOJİLERİ

SAN. TÌC. LTD. ŞTÌ.

Fener Mah. Bülent Ecevit Bulvarı No:48 Yıldırım

Plaza Muratpasa/ANTALYA

Ürün Adı /Modeller / Product Name / Models

Direktifi / Directive

Modülü/Kategori / Module / Category

: ESZE F2

: 2016/425 REGULATION

: B MODÜLÜ/ KATEGORİ III MODULE B / CATEGORY III

: M-2021-00139

Test Rapor No/ları / Test Report No

Ürün Tipi / Product Type:

 EN 149:2001+ A1:2009 Solunumla ilgili koruyucu cihazlar - Parçacıklara karşı koruma amaçlı filtreli yarım maskeler/ Respiratory protective devices - Filtering half masks to protect against particles

Ürünün Malzeme Bilgisi / Product Material Information: ESZE F2 model ürünleri kumaş, elastik kayış, burun klipsi ve filtre katmanı kullanılarak imal edilmiştir./ ESZE F2 model products are manufactured using fabric, elastic strap, nose clip, filter layer.

Volkan AKIN 09.02.2021

Karar Verici / Approver

Okan AKEL 09.02.2021

Şirket Müdürü / General manager





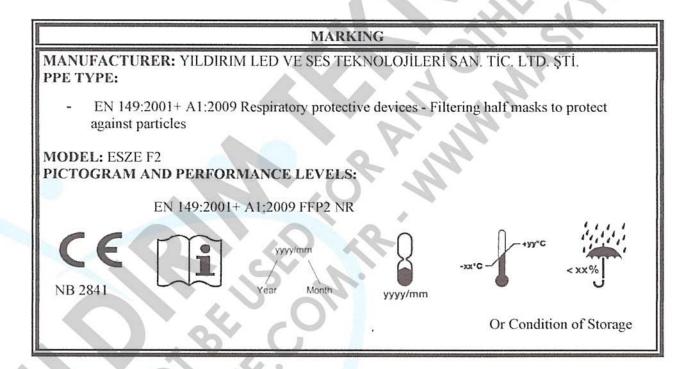
ATTACHMENTS (151-21-01)

To certify the PPE product at Category III level, C2 or D module is accompanied by applying one of the conformity assessment methods along with the EU Type Examination (Module B).

Model: ESZE F2

PPE SPECIFICATION	PERFORMANCE LEVELS
Classification	FFP2
Reusable / Single Shift Use	NR

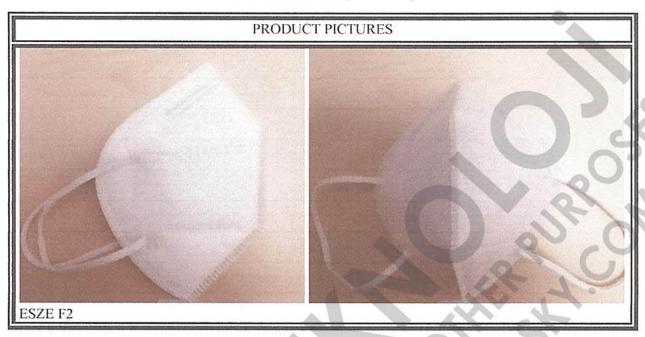
PPE produced as a single unit to fit an individual user, all the necessary instructions for manufacturing such PPE on the basis of the approved basic model:



MNA LABORATORIES SAN. TIC. LTD. ŞTİ declares that the above-mentioned product meets the requirements of the directive according to the EU Directive 2016/425, the safety of the product is covered by the conditions and use specified in this certificate and in the technical file.



ATTACHMENTS (151-21-01)



DOCUMENTS IN THE TECHNICAL FILE

- Basic Health Safety Requirements
- Risk Assessment
- Test Reports
- Technical Report



TECHNICAL EVALUATION REPORT (151-21-01)

Report No

:151-21-01

Report Date

:09.02.2021

Application No

:151-21-01

1. COMPANY INFORMATION:

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

Fener Mah. Bülent Ecevit Bulvarı No:48 Yıldırım Plaza Muratpaşa/ANTALYA

Tel: +90 850 840 93 55 Fax: +90 850 840 93 55

E-mail: info@yildirimteknoloji.net

2. PPE INFORMATION:

Disposable and non-sterile half mask made of particulate protection fitler material.

3. PPE TYPE IDENTIFICATION

EN 149:2001+A1:2009 Respiratory protective devices – Filtering half masks to protect against particles - Requirements, testing, marking

4. PPE PICTURES



ESZE F2

5. PPE DIMENSIONS:

ESZE F2 model has been found to be produced using standart sizes.

6. PPE PRODUCT MATERIAL INFORMATION:

The product is made of elastic strap, nonwoven fabric on the outer and inner layers and fitler material on the middle layer.

7. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS

- A visual inspection was made according to EN 149:2001 +A1:2009 for ergonomics.
- · Protection levels and degrees are defined by the manufacturer.
- Suitable construction materials were determined by visual inspection according to EN 149:2001 +A1:2009.



TECHNICAL EVALUATION REPORT (151-21-01)

8. ANALYSIS AND EVALUATIONS: EN 149:2001 +A1:2009

TESTS	PARAMETER PERFORMANCE LEVELS		RESULTS	PERFORMANCE LEVELS	EVALUATION		
		FFP1 FFP2 FFP3					
Part 7.3 Visual inspection	Shall also the ma supplied by the m	1754		rmation	Appropriate		PASS
Part 7.4 Packaging	Particle filtering half mask shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.			Appropriate		PASS	
Part 7.5 Material	When conditioned in accordance 8.3.1 & 8.3.2 the particle filter half mask shall not collapse.				Appropriate		PASS
Part 7.6 Cleaning and disinfecting	After cleaning and disinfecting the re-usable			isfy the	Not applicable	ILP I	Not applicable
Part 7.7 Practical performance	No negative comments should be made by the test subject regarding any of the criteria evaluated.			P (125)	Appropriate	, VE	PASS
Part 7.8 Finish of parts	Parts of the device likely to come into contact with the wearer shall have no sharp edge or burrs.				Appropriate	11,	PASS

TESTS	PARAMETER	PERFORMANCE LEVELS		RESULTS	PERFORMANCE LEVELS	EVALUATION	
		FFP1	FFP2	FFP3			
Part 7.9.1 Total inward leakage	At least 46 out of the 50 individual exercise result	<25	<11	<5	See the table below	FFP2	PASS
	At least 8 out of the 10 individual wearer arithmetic means	<22	<8	<2	See the table below	FFP2	PASS

	Total Inwar	d Leakage (%	6)			
	Exercise 1	Exercise 2	Exercise 3	Exercise 4	Exercise 5	Average
Subject 1 (As recieved)	7.0	7.2	7.8	6.3	7.8	7.2
Subject 2 (As recieved)	7.7	7.1	7.7	7.4	7.8	7.5
Subject 3 (As recieved)	7.8	7.8	7.9	5.1	8.1	7.3
Subject 4 (As recieved)	7.5	5.3	7.7	8.3	7.7	7.3
Subject 5 (As recieved)	6.2	5.3	7.9	6.9	8.0	6.9
Subject 6 (After temperature conditioning)	7.2	5.2	7.8	7.8	7.3	7.1
Subject 7 (After temperature conditioning)	7.5	7.8	7.5	8.0	7.5	7.7
Subject 8 (After temperature conditioning)	7.5	7.7	7.4	5.2	7.3	7.0
Subject 9 (After temperature conditioning)	7.6	7.4	7.7	5.0	7.5	7.0
Subject 10 (After temperature conditioning)	7.9	6.9	6.3	6.0	7.0	6.8

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TECHNICAL EVALUATION REPORT (151-21-01)

Subject facial dimensions

Subject Face Length (mm)		Face Width (mm)	Face Depth (mm)	Mouth Width (mm)
1	133	132	132	65
2	125	144	116	67
3	126	135	124	75
4	123	133	134	74
5	117	135	122	73
6	122	142	133	66
7	113	132	114	75
8	135	123	123	65
9	122	135	133	74
10	135	142	125	83

TESTS	7 - 35 - 36 - 36 - 36 - 36 - 36 - 36 - 36	Resident with the text of the		PERFORMANCE LEVELS	EVALUATION		
		FFP1	FFP2	FFP3		1. 7.5	
Part 7.9.2 Penetration of filter	Sodium chloride, 95 L/min %, max	% 20	% 6	%1	See the table below	FFP2	PASS
material	Paraffin oil, 95 L/min %, max	% 20	%6	%1	See the table below	FFP2	PASS

Penetration of filter material	Sodium Chloride (%)	Paraffin Oil (%)
As recieved	2.3	2.6
As recieved	2.7	2.6
As recieved	2.4	3.3
After the simulated wearing treatment	3.4	3.7
After the simulated wearing treatment	3.5	3.5
After the simulated wearing treatment	3.5	3.8
Mechanical strength and temperature conditioning	3.8	4.3
Mechanical strength and temperature conditioning	3.9	4.2
Mechanical strength and temperature conditioning	3.9	4.2

TESTS	PARAMETER	PERFORMANC	E LEVELS	RESULTS	PERFORMANCE	EVALUATION	
		FFP1 FFP2	FFP3		LEVELS		
Part 7.10 Compatibility with skin	Materials shall not be known to be likely to cause irritation or any other adverse effect to health			Appropriate	-	PASS	
Part 7.11 Flammibility	Mask shall not burn or not to continue to burn for more than 5 s			Flame not seen	-	PASS	
Part 7.12 Carbondioxide content of the inhalation air	Shall not exceed an average of % 1			0,78 0,67 0,83	-	PASS	
Part 7.13 Head harness	It can be donned and removed easily			Appropriate	-	PASS	



TECHNICAL EVALUATION REPORT (151-21-01)

Part 7.14 Field of vision	The field of vision shall acceptable in practical performance test.	Appropriate	-	PASS
Part 7.15 Exhalation valve(s)	It shall withstand axially a tensile force of 10 N apply for 10 s. If fitted, shall continue to operate correctly after a continuous exhalation flow of 300 L/min over a period of 30 s.	26		Not applicable

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE	EVALUATION
		FFP1	FFP2	FFP3		LEVELS	2
Part 7.16 Breathing	Inhalation 30L/min	0,6 mbar	0,7 mbar	1,0 mbar	See the table below	FFP2	PASS
Resistance	Inhalation 95L/min	2,1 mbar	2,4 mbar	3,0 mbar	See the table below	FFP2	PASS
	Exhalation 160L/min	3,0 mbar	3,0 mbar	3,0 mbar	See the table below	FFP2	PASS

Breathing Resistance (mbar)	Inhalation 30L/min	Inhalation 95L/min
As recieved	0,5	1,5
As recieved	0,5	1,5
As recieved	0,4	1,4
After temperature conditioning	0,4	1,5
After temperature conditioning	0,5	1,4
After temperature conditioning	0,5	1,4
After the simulated wearing treatment	0,5	1,5
After the simulated wearing treatment	0,4	1,5
After the simulated wearing treatment	0,5	1,4

Breathing Resistance 160L/min (mbar)	Facing directly ahead	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side
As recieved	2,3	2,3	2,3	2,3	2,2
As recieved	2,3	2,2	2,2	2,3	2,2
As recieved	2,2	2,2	2,2	2,2	2,2
After temperature conditioning	2,3	2,3	2,2	2,3	2,3
After temperature conditioning	2,3	2,3	2,2	2,2	2,2
After temperature conditioning	2,2	2,2	2,2	2,2	2,3
After the simulated wearing treatment	2,2	2,3	2,3	2,3	2,3
After the simulated wearing treatment	2,2	2,2	2,2	2,3	2,3
After the simulated wearing treatment	2,2	2,3	2,3	2,3	2,3



TECHNICAL EVALUATION REPORT (151-21-01)

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Part 7.17 Clogging	After clogging the inhalation resistances shall not exceed. (valved)	4 mbar	5 mbar	7 mbar	Not applicable		Not applicable
	The exhalation resistance shall not exceed 3 mbar at 160 L/ min continuous flow. (valved)				Not applicable		Not applicable
	After clogging the inhalation and exhalation resistances shall not exceed. (valveless)	3 mbar	4 mbar	5 mbar	Not applicable) (19	Not applicable
Part 7.18 Demountable part	All demountable pareadily connected possible by hand.	record neglect to			Not applicable	11/1/2	Not applicable

9. DECISION PROPOSAL

Analysis and examinations ESZE F2 model coded personal protective equipment; Respiratory Protective Devices EN 149:2001 +A1:2009- Filtered Half Masks for Protection Against Particles - Properties, Experiments and Marking standards are evaluated. It is recommended to be certified at the performance levels specified as a result of technical evaluations.

10. ATTACHMENTS

- Basic Health Safety Requirements
- Risk Assessment
- Test Reports
- User Instruction

CONTROLLER : VOLKAN AKIN

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DATE : 09.02.2021