Notified Body Number: 2841

AB Tip İnceleme Sertifikası
EU Type-Examination Certificate

Belge No / *Certificate No* : 46-21-01
Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /
Certification Date / Certificate Validity Date : 28.05.2021-28.05.2026
Belge Geçerlilik Tarihi / *Document Validity Period*: 5 yıl / *5 years*
Firma Unvanı ve Adresi /
Company Name and Address : EKOMED TEKSTİL VE MEDİKAL TİC. A.Ş. Şerifali Mah. Miras Sok. Lesafre Apt. No: 20/1 Ümraniye / İSTANBUL
Ürün Adı /Modeller / *Product Name / Models* : EKM-FFP2-004
Direktifi / *Directive* : 2016/425 REGULATION
Modülü/Kategori / *Module / Category* : B MODÜLÜ/ KATEGORİ III
MODULE B / CATEGORY III
Test Rapor No/ları / *Test Report No* : MNA M-2021-01032
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*: EKM-FFP2-004 model ürünleri kumaş, elastik kayış, burun klipsi ve filtre katmanı kullanılarak imal edilmiştir./ *EKM-FFP2-004 model products are manufactured using fabric, elastic strap, nose clip, filter layer.*

Volkan AKIN	***Okan AKEL***
28.05.2021	***28.05.2021***
Karar Verici / Approver	***Şirket Müdürü / General manager***

Notified Body Number: 2841

ATTACHMENTS (46-21-01)

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 : EKM-FFP2-004

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:

MARKING

MANUFACTURER: EKOMED TEKSTİL VE MEDİKAL TİC. A.Ş.
PPE TYPE:

- EN 149:2001+ A1:2009 Respiratory protective devices - Filtering half masks to protect against particles

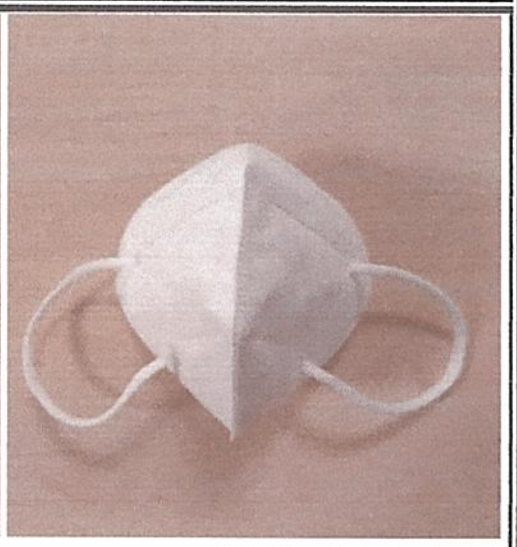
MODEL: EKM-FFP2-004
PRODUCT SIZE: Standard
PICTOGRAM AND PERFORMANCE LEVELS:

EN 149:2001+ A1:2009 FFP2 NR

Or Condition of Storage

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 (46-21-01)

PRODUCT PICTURES

EKM-FFP2-004

DOCUMENTS IN THE TECHNICAL FILE
- Basic Health Safety Requirements - Risk Assessment - Test Reports - Technical Report

Report No : 46-21-01

Report Date : 28.05.2021

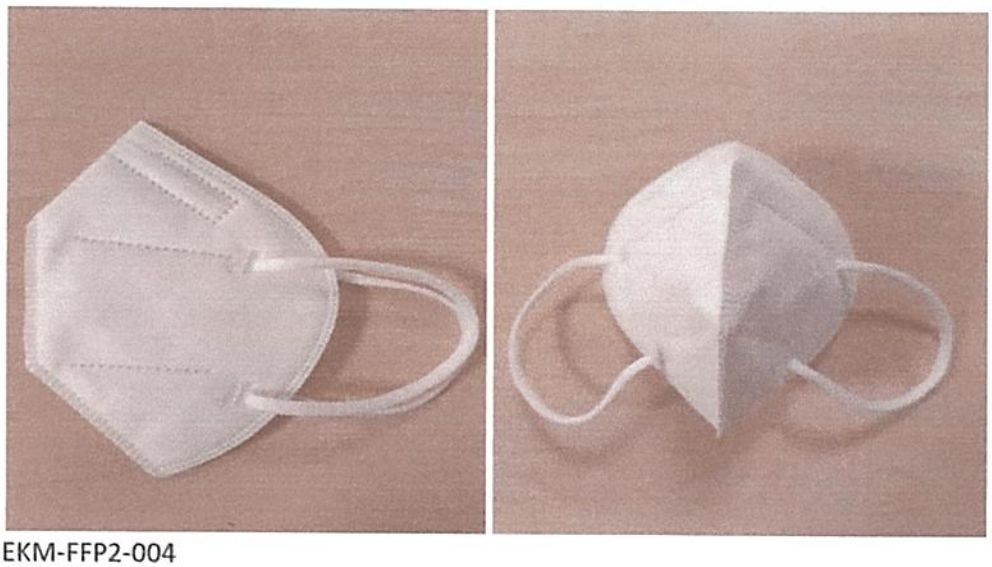
Application No : 46-21-01

1. **COMPANY INFORMATION:**
   EKOMED TEKSTİL VE MEDİKAL TİC. A.Ş.
   Şerifali Mah. Miras Sok. Lesafre Apt. No: 20/1 Ümraniye / İSTANBUL

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**



EKM-FFP2-004

5. **PPE DIMENSIONS:**
   EKM-FFP2-004 model has been found to be produced using standard 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.

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 marking and the information supplied by the manufacturer				Appropriate	-	PASS
Banned Azo Dyes	< 30 mg/kg				Not applicable	-	Not applicable
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 particle filtering half mask shall satisfy the penetration requirement of the relevant class.				Not applicable	-	Not applicable
Part 7.7 Practical performance	No negative comments should be made by the test subject regarding any of the criteria evaluated.				Appropriate	-	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	-	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 Inward Leakage (%)						
	Exercise 1	Exercise 2	Exercise 3	Exercise 4	Exercise 5	Average
Subject 1 (As recieved)	8,0	7,0	6,2	8,2	6,5	7,2
Subject 2 (As recieved)	7,7	5,3	5,8	6,5	6,4	6,3
Subject 3 (As recieved)	7,4	8,6	5,9	8,2	8,6	7,7
Subject 4 (As recieved)	7,3	8,0	7,8	8,3	8,6	8,0
Subject 5 (As recieved)	7,1	8,3	7,7	5,4	7,2	7,1
Subject 6 (After temperature conditioning)	8,6	9,3	8,8	9,5	8,7	9,0
Subject 7 (After temperature conditioning)	7,4	7,6	7,3	6,3	7,2	7,2

Subject 8 (After temperature conditioning)	7,5	8,6	7,1	7,2	7,4	7,6
Subject 9 (After temperature conditioning)	6,1	8,6	8,6	8,2	8,8	8,1
Subject 10 (After temperature conditioning)	4,8	5,1	4,5	5,5	4,2	4,8

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	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Part 7.9.2 Penetration of filter material	Sodium chloride, 95 L/min %, max	% 20	% 6	% 1	See the table below	FFP2	PASS
	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	2,0	2,4
As recieved	2,5	2,6
As recieved	2,1	2,5
After the simulated wearing treatment	2,4	2,5
After the simulated wearing treatment	2,4	2,6
After the simulated wearing treatment	2,6	2,6
Mechanical strength and temperature conditioning	3,2	3,3
Mechanical strength and temperature conditioning	3,2	3,5
Mechanical strength and temperature conditioning	3,4	3,6

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
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				0,83 0,82 0,81	-	PASS
Part 7.13	It can be donned and removed easily				Appropriate	-	PASS

Head harness				
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.	Not applicable	-	Not applicable

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Part 7.16 Breathing Resistance	Inhalation 30L/min	0,6 mbar	0,7 mbar	1,0 mbar	See the table below	FFP2	PASS
	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	2,1
As recieved	0,6	2,2
As recieved	0,5	2,1
After temperature conditioning	0,5	2,1
After temperature conditioning	0,5	2,1
After temperature conditioning	0,5	2,2
After the simulated wearing treatment	0,5	2,1
After the simulated wearing treatment	0,6	2,1
After the simulated wearing treatment	0,6	2,2

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	2,7	2,8	2,8	2,8	2,8
As recieved	2,7	2,7	2,7	2,8	2,7
As recieved	2,7	2,7	2,7	2,7	2,7
After temperature conditioning	2,7	2,7	2,8	2,7	2,8
After temperature conditioning	2,8	2,7	2,8	2,8	2,8
After temperature conditioning	2,7	2,7	2,7	2,7	2,7
After the simulated wearing treatment	2,7	2,8	2,7	2,8	2,7
After the simulated wearing treatment	2,7	2,8	2,7	2,7	2,7
After the simulated wearing treatment	2,8	2,7	2,7	2,7	2,7

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	-	Not applicable
Part 7.18 Demountable part	All demountable parts (if fitted) shall be readily connected and secured were possible by hand.				Not applicable	-	Not applicable

9. DECISION PROPOSAL

Analysis and examinations EKM-FFP2-004 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
- User Instruction

CONTROLLER : **VOLKAN AKIN**

SING :

DATE : **28.05.2021**