

Notified Body Number: 2841

CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT CHECKS AT RANDOM INTERVALS (MODULE C2)

MODÜL C2 - ÜRETİMİN DÂHİLÎ KONTROLÜ VE ÜRÜNÜN RASTGELE ARALIKLARLA DENETİMLİ MUAYENESİNE DAYALI TİPE UYGUNLUK

Belge No / Certificate No
Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /
Certification Date / Certificate Validity Date
Belge Geçerlilik Tarihi / Document Validity Period
Firma Unvanı ve Adresi /
Company Name and Address

: 253-21-01-01 : 01.02.2022-01.02.2023

: 1 yıl / 1 year

Ürün Adı/Modeller / Product Name / Models Direktifi / Directive Modülü/Kategori / Module / Category : ANKA PROMOSYON ÜRÜNLERİ VE MATBAA MALZEMELERİ SANAYİ TİCARET LİMİTED ŞİRKETİ

Fevzi Çakmak Mah. 10576. Sk. No: 66/D , 42050 Karatay/KONYA

Modülü/Kategori / Module / Category

: DM-33

: 2016/425 REGULATION

: C2 MODÜLÜ/ KATEGORİ III MODULE C2 / CATEGORY III

Teknik Değerlendirme Rapor No/ Technical Evaluation Report No Ürün Tipi / Product Type:

: MNA 253-21-01-01

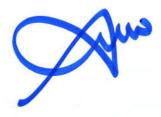
- EN 149:2001+ A1:2009 Solunumla ilgili koruyucu cihazlar- Parçacıklara karşı koruma amaçlı filtreli yarım maskeler/ Respiratory protective devices - Filtering half masks to protect against particles

Ürünün Malzeme Bilgisi / *Product Material Information*: DM-33 model ürünleri kumaş, elastik kayış, burun klipsi, filtre katmanı kullanılarak imal edilmiştir. / DM-33 products are manufactured using fabric, elastic strap, nose clip, filter layer.

Volkan AKIN 01.02.2022 Karar Verici / Approver

Okan AKEL 01.02.2022 Şirket Müdürü / General manager











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CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT **CHECK AT RANDOM INTERVALS**

(MODULE C2, ANNEX VII) (253-21-01-01)

Report No

: 253-21-01-01

Report Date

:01.02.2022

Application No

: 253-21-01-01

1. COMPANY INFORMATION:

ANKA PROMOSYON ÜRÜNLERİ VE MATBAA MALZEMELERİ SANAYİ TİCARET LİMİTED ŞİRKETİ Fevzi Çakmak Mah. 10576. Sk. No: 66/D , 42050 Karatay/KONYA

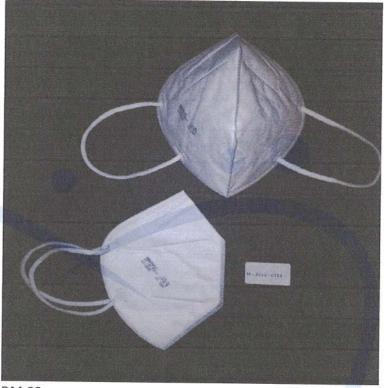
2. PPE INFORMATION:

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



DM-33

5. PPE DIMENSIONS:

DM-33 model has been found to be produced using standard sizes.

6. PPE PRODUCT MATERIAL INFORMATION:

The mask 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.

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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	PERFORMANC LEVELS FFP1 FFP2	FFP3	RESULTS	PERFORMANCE LEVELS	EVALUATION
Banned Azo Dyes	< 30 mg/kg			-	-	Not applicable
Part 7.3 Visual inspection	Shall also the mark supplied by the ma		nation	Appropriate	-	PASS
Part 7.4 Packaging	Particle filtering ha for sale packaged are protected agai and contamination	n such a way that nst mechanical da	they	Appropriate	-	PASS
Part 7.5 Material	When conditioned 8.3.2 the particle f collapse.			Appropriate	-	PASS
Part 7.6 Cleaning and disinfecting	After cleaning and disinfecting the re-usable			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 contact with the we edge or burrs.			Appropriate	-	PASS

TESTS	PARAMETER	PERFC LEVEL	ORMAN S	CE	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
Æ	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 received)	4,4	5,5	5,4	6,3	5,4	5,4					
Subject 2 (As received)	4,7	5,0	6,0	4,2	4,0	4,8					
Subject 3 (As received)	5,2	4,7	5,8	2,6	4,7	4,6					
Subject 4 (As received)	6,3	6,7	4,6	4,5	6,3	5,7					



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Subject 5 (As received)	6,5	3,7	5,8	5,6	4,0	5,1
Subject 6 (After temperature conditioning)	5,9	6,3	3,5	3,7	5,7	5,0
Subject 7 (After temperature conditioning)	6,1	6,9	5,7	5,7	6,0	6,1
Subject 8 (After temperature conditioning)	5,4	5,7	6,9	7,5	4,7	6,0
Subject 9 (After temperature conditioning)	5,3	5,5	5,4	5,4	5,3	5,4
Subject 10 (After temperature conditioning)	6,1	5,3	5,1	6,1	3,4	5,2

Subject facial dimensions

Subject	Face Length (mm)	Face Width (mm)	Face Depth (mm)	Mouth Width
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	PARAMETER	PERFORMANCE LEVELS			RESULTS PERFORMANCE LEVELS		EVALUATION
	FFP1	FFP2	FFP3	7			
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 received	2,5	2,6
As received	2,2	2,6
As received	2,4	2,7
After the simulated wearing treatment	2,4	2,4
After the simulated wearing treatment	2,6	2,8
After the simulated wearing treatment	2,3	2,6
Mechanical strength and temperature conditioning	3,9	4,1
Mechanical strength and temperature conditioning	3,5	4,0
Mechanical strength and temperature conditioning	3,6	4,1

TESTS PARAMETER	PERFO	ORMAN S	CE	RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3		



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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	0,75 0,79 0,70	-	PASS
Part 7.13 Head harness	It can be donned and removed easily	Appropriate	-	PASS
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	PARAMETER	PERFORMANCE LEVELS		RESULTS	PERFORMANCE LEVELS	EVALUATION	
	FFP1	FFP2	FFP3				
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 received	0,5	1,6
As received	0,5	1.7
As received	0,4	1,6
After temperature conditioning	0,4	1,6
After temperature conditioning	0,4	1,6
After temperature conditioning	0,5	1,7
After the simulated wearing treatment	0,5	1,7
After the simulated wearing treatment	0,4	1,6
After the simulated wearing treatment	0,5	1,7

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 received	2,7	2,6	2,7	2,7	2,6
As received	2,6	2,7	2,6	2,6	2,6
As received	2,7	2,6	2,6	2,6	2,6
After temperature conditioning	2,6	2,7	2,7	2,7	2,7
After temperature conditioning	2,6	2,7	2,7	2,7	2,7
After temperature conditioning	2,6	2,6	2,6	2,6	2,6



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After the simulated wearing treatment	2,7	2,6	2,6	2,6	2,6
After the simulated wearing treatment	2,6	2,7	2,7	2.7	2.7
After the simulated wearing treatment	2,7	2,6	2,6	2.6	2,6

TESTS PARAME	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3		3	
Clogging in reinforce in the control of the control	After clogging the inhalation resistances shall not exceed. (valved)	4 mba r	5 mba r	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 mba r	4 mba r	5 mbar	Not applicable	-	Not applicable
Part 7.18 Demountable part	All demountable par readily connected possible by hand.				Not applicable	-	Not applicable

9. DECISION

Analysis and examinations DM-33 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. The homogeneity of the production was monitored at the performance levels determined as a result of the technical evaluations made within the scope of MODULE C2.

10. ATTACHMENTS

- **Basic Health Safety Requirements**
- Risk Assessment
- Test Reports (M-2022-0121)
- User Instruction

CONTROLLER

: Volkan AKIN

SIGNATURE

DATE

: 01.02.2022









EC DECLARATION OF CONFIRMITY

ANKA PROMOSYON ÜRÜNLERİ VE MATB. MALZ. SAN. TİC. LTD. ŞTİ. FEVZİ ÇAKMAK MAH.10576 SK.NO:66/D 42050 KARATAY/KONYA

Product Defination : Protective Mask

Brand Name

: DOST

Model

: DM-33

Classification

: FFP2 NR

Barcode Number : 8682759618174

To which this declaration relates are in conformity with the requirements of the following directives;

Personal Protective Equipment Regulation (EU) 2016/425 Annex III

We are declaring our product suitable for European conditions and accepting all responsibilities about our product. The conformity was checked for Personal Protective Equipment Regulation in accordance with the following harmonized EN standard.

EN 149:2001 + A1:2009

The EU type examination document has been issued by MNA LABORATORIES with the Notified Body Number: 2841. Codes of the analysis reports of the products M-2021-01006. The number of the EU Type Examination document is 253-21-01 in addition, since the product is in category III group, the process monitoring is provided by MNA LABORATORIES for the internal control of the product production and the evaluation of the product within the scope of confirmity to type (Module C2) based on supervised inspection at random intervals.

Person responsable for making this declaration

Name, Surname : Yasin Emre Yıldırım

Position

: General Manager

Date

: 28.05.2021



