Notify Body No: 2841

Product TS EN ISO/IEC 17065 AB-0128-U

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*	: 19013029
Belgelendirme Tarihi - Bir Sonraki Belge Tarihi / *Certification Date / Certificate Validity Date*	: 03.02.2025-03.02.2026
Belge Geçerlilik Tarihi / *Document Validity Period*	: 1 yıl / *1 years*
Firma Unvanı ve Adresi / *Company Name and Address*	: MFA İŞ GÜVENLİĞİ MEDİKAL A.Ş. Elvanpazarcık Beldesi Hayat Mah. Baruthane Caddesi No:21/1, 67990 Merkez- Zonguldak
Marka /Modeller / *Brand / Models*	: ZAGOR ZR 5030, ZAGOR ZR 5035
Direktifi / *Directive*	: 2016/425 REGULATION
Modülü/Kategori / *Module / Category*	: MODÜL C2/ KATEGORİ III *MODULE C2 / CATEGORY III*
Teknik Değerlendirme Rapor No/ *Technical Evaluation Report No*	: MNA 19013029

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* ZAGOR ZR 5030, ZAGOR ZR 5035 model ürünleri kumaş, elastik kayış, soluk verme valfi, burun klipsi ve filtre katmanı kullanılarak imal edilmiştir./ *ZAGOR ZR 5030, ZAGOR ZR 5035 model products are manufactured using fabric, elastic strap, nose clip, exhalation valve and filter layer.*

Karar Verici / Approver

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Şirket Müdürü / General Manager

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Notified Body Number: 2841

CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT CHECK AT RANDOM INTERVALS (MODULE C2, ANNEX VII) (19013029)

Report No : 19013029

Report Date : 03.02.2025

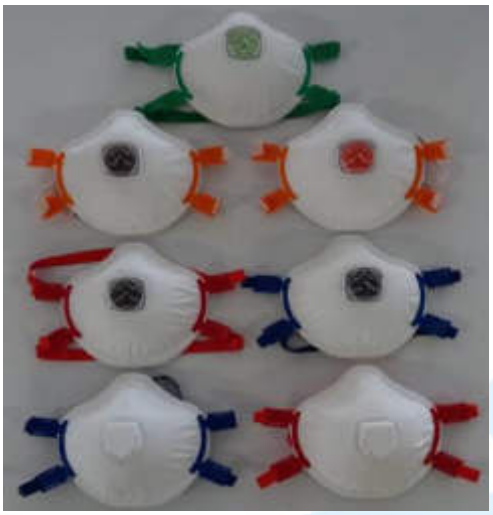
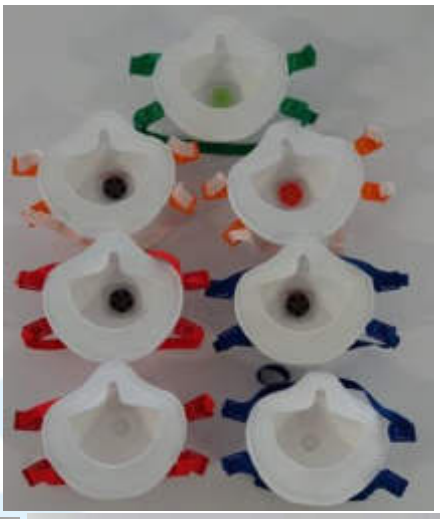
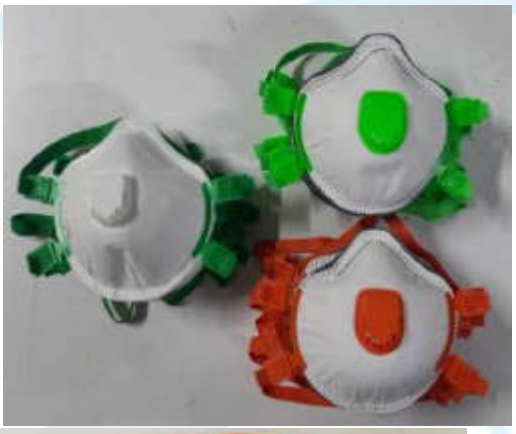
Application No : 19013029

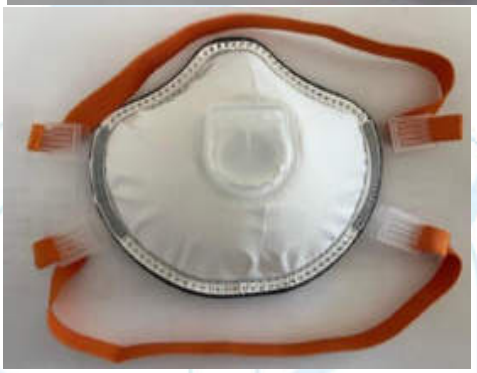
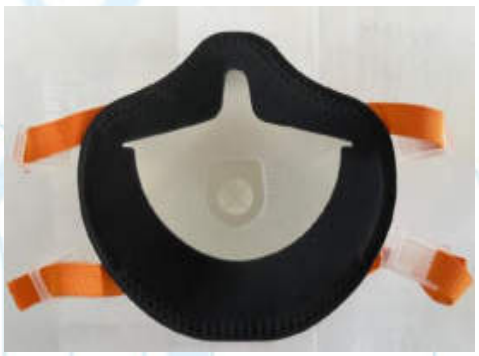
1. **COMPANY INFORMATION:**
   MFA İŞ GÜVENLİĞİ MEDİKAL A.Ş.
   Elvanpazarcık Beldesi Hayat Mah. Baruthane Caddesi No:21/1, 67990 Merkez- Zonguldak

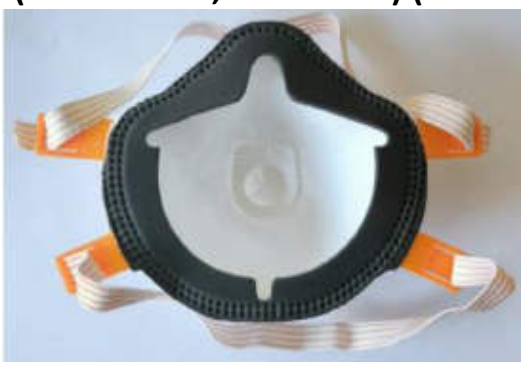
2. **PPE INFORMATION:**
   Disposable and non-sterile half mask made of particulate protection filter material.

3. **PPE TYPE IDENTIFICATION**
   EN 149:2001+A1:2009 Respiratory protective devices – Filtering half masks to protect against particles - Requirements, testing, marking

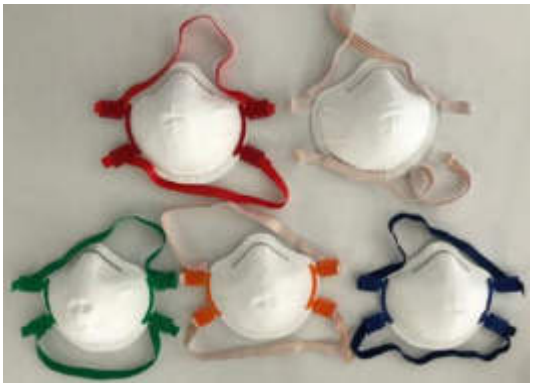
4. **PPE PICTURE**

ZAGOR ZR 5030




ZAGOR ZR 5035

5. PPE DIMENSIONS:

ZAGOR ZR 5030, ZAGOR ZR 5035 model has been found to be produced using standard size.

6. PPE PRODUCT MATERIAL INFORMATION:

The product is made of elastic strap, exhalation valve, nonwoven fabric on the outer and inner layers and filter 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 EVALUATION AND MARKING:

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	Red Fabric Earloop+Blue Fabric Earloop,Orange Fabric Earloop+Green Fabric Earloop< 30 mg/kg				<5 mg/kg	-	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 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	FFP3	PASS
	At least 8 out of the 10 individual wearer arithmetic means	≤22	≤8	≤2	See the table below	FFP3	PASS

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Total Inward Leakage (%)						
	Exercise 1	Exercise 2	Exercise 3	Exercise 4	Exercise 5	Average
Subject 1 (As received)	1,5	1,0	1,2	1,4	1,3	1,3
Subject 2 (As received)	1,2	1,2	1,7	1,7	1,0	1,4
Subject 3 (As received)	1,1	1,7	1,1	1,0	1,3	1,2
Subject 4 (As received)	1,0	1,8	1,5	1,0	1,3	1,3
Subject 5 (As received)	1,2	1,0	1,1	1,1	0,8	1,0
Subject 6 (After temperature conditioning)	1,0	1,0	1,3	1,2	1,2	1,1
Subject 7 (After temperature conditioning)	1,5	1,3	1,2	1,4	1,0	1,3
Subject 8 (After temperature conditioning)	0,6	1,6	1,2	1,7	1,0	1,2
Subject 9 (After temperature conditioning)	1,0	1,3	1,5	1,2	1,3	1,3
Subject 10 (After temperature conditioning)	1,4	1,1	1,2	0,9	1,3	1,2

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Total Inward Leakage (%)						
	Exercise 1	Exercise 2	Exercise 3	Exercise 4	Exercise 5	Average
Subject 1 (As received)	1,0	1,5	1,7	1,9	2,0	1,6
Subject 2 (As received)	1,7	1,7	1,9	2,1	1,0	1,7
Subject 3 (As received)	1,6	1,1	1,6	2,2	2,0	1,7
Subject 4 (As received)	1,5	1,2	2,0	1,5	1,4	1,5
Subject 5 (As received)	1,7	1,5	1,6	1,8	1,7	1,7
Subject 6 (After temperature conditioning)	1,5	1,5	1,8	1,7	1,7	1,6

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

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	FFP3	PASS
	Paraffin oil, 95 L/min %, max	% 20	% 6	% 1	See the table below	FFP3	PASS

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Penetration of filter material	Sodium Chloride (%)	Paraffin Oil (%)
As received	0,3	0,5
As received	0,4	0,6
As received	0,2	0,6
After the simulated wearing treatment	0,3	0,4
After the simulated wearing treatment	0,2	0,5
After the simulated wearing treatment	0,3	0,5
Mechanical strength and temperature conditioning (120 mg)	0,4	0,6
Mechanical strength and temperature conditioning (120 mg)	0,4	0,7
Mechanical strength and temperature conditioning (120 mg)	0,5	0,6
Clogging (with valve)	0,02	0,04
Clogging (with valve)	0,02	0,04
Clogging (with valve)	0,03	0,04

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Penetration of filter material	Sodium Chloride (%)	Paraffin Oil (%)
As received	0,2	0,3
As received	0,2	0,4
As received	0,1	0,4
After the simulated wearing treatment	0,1	0,3
After the simulated wearing treatment	0,2	0,4
After the simulated wearing treatment	0,2	0,4
Mechanical strength and temperature conditioning (120 mg)	0,3	0,5
Mechanical strength and temperature conditioning (120 mg)	0,3	0,6
Mechanical strength and temperature conditioning (120 mg)	0,4	0,6

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				**5030** 0,58 0,54 0,52 **5035** 0,57 0,52 0,55	-	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.				Appropriate	-	PASS

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	FFP3	PASS
	Inhalation 95L/min	2,1 mbar	2,4 mbar	3,0 mbar	See the table below	FFP3	PASS
	Exhalation 160L/min	3,0 mbar	3,0 mbar	3,0 mbar	See the table below	FFP3	PASS

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Breathing Resistance (mbar)	Inhalation 30L/min	Inhalation 95L/min
As received	0,4	1,4
As received	0,4	1,3
As received	0,3	1,3
After temperature conditioning	0,4	1,4
After temperature conditioning	0,3	1,3
After temperature conditioning	0,3	1,3
After the simulated wearing treatment	0,3	1,3
After the simulated wearing treatment	0,4	1,3
After the simulated wearing treatment	0,3	1,3
After the flow conditioning (with valve)	0,3	1,3
After the flow conditioning (with valve)	0,3	1,3
After the flow conditioning (with valve)	0,3	1,4

Breathing Resistance After Clogging (mbar)	Inhalation 95 L/min
Clogging Breathing Resistance (with valve)	1,1
Clogging Breathing Resistance (with valve)	1,0
Clogging Breathing Resistance (with valve)	1,1

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	1,2	1,1	1,2	1,2	1,1
As received	1,2	1,2	1,1	1,2	1,1
As received	1,1	1,2	1,2	1,1	1,2
After temperature conditioning	1,2	1,1	1,2	1,1	1,1
After temperature conditioning	1,2	1,1	1,1	1,2	1,1
After temperature conditioning	1,1	1,2	1,2	1,2	1,2
After the simulated wearing treatment	1,2	1,1	1,2	1,2	1,1
After the simulated wearing treatment	1,1	1,2	1,1	1,2	1,1
After the simulated wearing treatment	1,1	1,1	1,2	1,1	1,2
After the flow conditioning (with valve)	1,2	1,1	1,1	1,2	1,1
After the flow conditioning (with valve)	1,2	1,1	1,1	1,2	1,1
After the flow conditioning (with valve)	1,1	1,2	1,2	1,2	1,1

Breathing Resistance After Clogging 160 L/min (mbar) Exhalation	Facing directly ahead	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side
Clogging Breathing Resistance (with valve)	0,9	0,9	0,9	0,9	0,9
Clogging Breathing Resistance (with valve)	0,9	0,9	0,8	0,9	0,8
Clogging Breathing Resistance (with valve)	1,0	1,0	1,0	0,9	0,9

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Breathing Resistance (mbar)	Inhalation 30L/min	Inhalation 95L/min
As received	0,3	1,3
As received	0,4	1,4
As received	0,3	1,4
After temperature conditioning	0,4	1,4
After temperature conditioning	0,4	1,4
After temperature conditioning	0,4	1,4
After the simulated wearing treatment	0,3	1,3
After the simulated wearing treatment	0,3	1,3
After the simulated wearing treatment	0,4	1,4
After the flow conditioning (with valve)	-	-
After the flow conditioning (with valve)	-	-
After the flow conditioning (with valve)	-	-

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	2,3	2,4	2,4	2,3	2,4
As received	2,3	2,4	2,3	2,3	2,4
As received	2,4	2,3	2,4	2,3	2,3
After temperature conditioning	2,3	2,4	2,4	2,4	2,3
After temperature conditioning	2,3	2,4	2,4	2,3	2,4
After temperature conditioning	2,3	2,4	2,3	2,4	2,3
After the simulated wearing treatment	2,3	2,3	2,4	2,3	2,3
After the simulated wearing treatment	2,3	2,4	2,3	2,4	2,3

After the simulated wearing treatment	2,3	2,3	2,4	2,3	2,4
After the flow conditioning (with valve)	-	-	-	-	-
After the flow conditioning (with valve)	-	-	-	-	-
After the flow conditioning (with valve)	-	-	-	-	-

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP 1	FFP 2	FFP3			
Part 7.17 Clogging	After clogging the inhalation resistances shall not exceed. (valved)	4 mbar	5 mbar	7 mbar	1,1 mbar	D	PASS
	The exhalation resistance shall not exceed 3 mbar at 160 L/ min continuous flow. (valved)				1,0 mbar	D	PASS
	After clogging the inhalation and exhalation resistances shall not exceed. (valveless)	3 mbar	4 mbar	5 mbar	-	-	-
Part 7.18 Demountable part	All demountable parts (if fitted) shall be readily connected and secured were possible by hand.				Not applicable	-	Not applicable
Part 9 Marking	The packaging information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.				Appropriate	-	PASS

9. ATTACHMENTS

- Test Report (M-2024-0215, M-2024-0216, M-2024-0556, 689-2-23-1)

CONTROLLER : Digitally signed by
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DATE : Date: 2025.02.03 14:06:29 +03'00'