



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

Marka /Modeller / Brand / Models

Direktifi / *Directive* Modülü/Kategori / *Module / Category*

Teknik Değerlendirme Rapor No/ *Technical Evaluation Report No*



: 64013041

: 03.02.2025-03.02.2026 : 1 yıl / *1 years*

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

: ZAGOR ZR 5020, ZAGOR ZR 5025, ZAGOR ZR 7007 AC : 2016/425 REGULATION : MODÜL C2/ KATEGORİ III *MODULE C2 / CATEGORY III*

: MNA 64013041

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 5020, ZAGOR ZR 5025, ZAGOR ZR 7007 AC model ürünleri kumaş, elastik kayış, soluk verme valfi, burun klipsi ve filtre katmanı kullanılarak imal edilmiştir./ ZAGOR ZR 5020, ZAGOR ZR 5025, ZAGOR ZR 7007 AC model products are manufactured using fabric, elastic strap, nose clip, exhalation valve and filter layer.

Karar Verici / Approver

Şirket Müdürü / General Manager





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U-Form-002/Rev.07/03.07.2024 This document has been signed electronically in accordance with the Electronic Signature Law No. 5070. The document can be checked at https://www.mnalab.com/en/sertifika-sorgula CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT CHECK AT RANDOM INTERVALS Notified Body Number: 2841 (MODULE C2, ANNEX VII) (64013041)

Report No : 64013041

Report Date : 03.02.2025

Application No : 64013041

 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 PICTURES



U-FRM-056.REV.02./23.03.2023



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ZAGOR ZR 5025



ZAGOR ZR 7007 AC

5. PPE DIMENSIONS:

ZAGOR ZR 5020, ZAGOR ZR 5025, ZAGOR ZR 7007 AC 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		RESULTS	PERFORMAN	EVALUATIO
		LEVELS			CE LEVELS	Ν
		FFP1 FFP	FFP3			
1		2				
Part 7.3	Shall also the markin	g and the inf	ormation	Appropriate	-	PASS
Visual	supplied by the manufacturer					
inspection						
Banned Azo	Blue fabric+Red	fabric,Oran	ge-White	<5 mg/kg	-	PASS
Dyes	fabric+Green fabric< 3	80 mg/kg	1 ch			



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Part 7.4 Particle filtering half mask shall be offered for Appropriate PASS sale packaged in such a way that they are Packaging protected against mechanical damage and contamination before use. When conditioned in accordance 8.3.1 & Part 7.5 Appropriate -PASS Material 8.3.2 the particle filter half mask shall not collapse. Part 7.6 After cleaning and disinfecting the re-usable Not applicable Not applicable particle filtering half mask shall satisfy the Cleaning and penetration requirement of the relevant disinfecting class. Part 7.7 No negative comments should be made by Appropriate PASS the test subject regarding any of the criteria Practical performance evaluated. Part 7.8 Parts of the device likely to come into contact Appropriate PASS -Finish of parts with the wearer shall have no sharp edge or burrs.

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

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

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



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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	Sodium chloride, 95	% 20	% 6	% 1	See the table	FFP2	PASS
Penetration	L/min				below		
of filter	%, max						
material	Paraffin oil, 95 L/min	% 20	% 6	% 1	See the table	FFP2	PASS
	%, max				below		

Penetration of filter material	Sodium Chloride (%)	Paraffin Oil (%)
As received	0,8	1,2
As received	1,2	1,1
As received	1,1	1,4
After the simulated wearing treatment	1,0	1,3
After the simulated wearing treatment	0,9	1,3
After the simulated wearing treatment	1,3	1,4
Mechanical strength and temperature conditioning (120 mg)	2,5	2,8
Mechanical strength and temperature conditioning (120 mg)	2,2	2,6
Mechanical strength and temperature conditioning (120 mg)	2,4	2,9
Clogging (with valve)	0,02	0,04
Clogging (with valve)	0,02	0,04
Clogging (with valve)	0,03	0,04

TESTS	PARAMETER	PERFORMANCE		RESULTS	PERFORMANCE	EVALUATION	
		FFP1	FFP2	FFP3			
Part 7.10	Materials shall not b	e know	n to be	likely to	Appropriate	-	PASS
Compatibility	cause irritation or an	y other a	adverse	effect to			
with skin	health						
Part 7.11	Mask shall not burn o	or not to	continue	e to burn	Flame not	-	PASS
Flammibility	for more than 5 s				seen		
Part 7.12	Shall not exceed an	average	of % 1		0,55	-	PASS
Carbondioxide					0,51		
content of the					0,52		
inhalation air							
Part 7.13	It can be donned and	l remove	ed easily	/	Appropriate	-	PASS
Head harness			- 1	71			
Part 7.14	The field of vision sha	all accep	table in	practical	Appropriate	-	PASS
Field of vision	performance test.						
Part 7.15	It shall withstand axi	ally a te	nsile for	ce of 10	Appropriate	-	PASS
Exhalation	N apply for 10 s.	S . 7	6 B.			~	
valve(s)	It titted, shall contin	ue to o	perate of	correctly			
	atter a continuous	exnalati	on tiow	of 300			
	L/min over a period o	01 30 S.		100			



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

Breathing Resistance (mbar)	Inhalation 30L/min	Inhalation 95L/min
As received	0,4	1,6
As received	0,4	1,6
As received	0,4	1,5
After temperature conditioning	0,3	1,5
After temperature conditioning	0,4	1,5
After temperature conditioning	0,4	1,6
After the simulated wearing treatment	0,3	1,6
After the simulated wearing treatment	0,4	1,5
After the simulated wearing treatment	0,3	1,5
After the flow conditioning	0,4	1,6
After the flow conditioning	0,4	1,5
After the flow conditioning	0.3	1,5

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	1,2	1,2	1,2	1,3
As received	1,2	1,3	1,2	1,2	1,2
As received	1,2	1,2	1,3	1,2	1,2
After temperature conditioning	1,2	1,3	1,3	1,3	1,3
After temperature conditioning	1,3	1,3	1,3	1,3	1,3
After temperature conditioning	1,3	1,3	1,2	1,3	1,2
After the simulated wearing treatment	1,3	1,2	1,3	1,2	1,3
After the simulated wearing treatment	1,3	1,3	1,3	1,3	1,2
After the simulated wearing treatment	1,3	1,2	1,3	1,2	1,3
After the flow conditioning	1,2	1,3	1,2	1,3	1,3
After the flow conditioning	1,3	1,2	1,3	1,3	1,3
After the flow conditioning	1,2	1,3	1,3	1,3	1,2



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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

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

9. ATTACHMENTS

Test Report (M-2024-0383, M-2024-0384, 689-8-23-1) •

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