MNA LABORATUVARLARI

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*	: 258-21-01-01
Belgelendirme Tarihi - Bir Sonraki Belge Tarihi / *Certification Date / Certificate Validity Date*	: 01.04.2022-01.04.2023
Belge Geçerlilik Tarihi / *Document Validity Period*	: 1 yıl / *1 years*
Firma Unvanı ve Adresi / *Company Name and Address*	: PRİZMANET MEDİKAL SAN. TİC. İTH. İHR. LTD. ŞTİ. Yahya Kemal Mah. Okul Cad. No:13/15, Kağıthane/İstanbul, TÜRKİYE
Ürün Adı /Modeller / *Product Name / Models*	: Q-ZER N001(WHITE), N005(BLACK), N006(CHERRY), N007(ORANGE), N0011(PATTERNED)
Direktifi / *Directive*	: 2016/425 REGULATION
Modülü/Kategori / *Module / Category*	: C2 MODÜLÜ/ KATEGORİ III *MODULE C2 / CATEGORY III*
Teknik Değerlendirme Rapor No/ *Technical Evaluation Report No*	: MNA 258-21-01-01

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***: Q-ZER N001(WHITE), N005(BLACK), N006(CHERRY), N007(ORANGE), N0011(PATTERNED) Mask model ürünleri kumaş, elastik kayış, burun klipsi ve filtre katmanı kullanılarak imal edilmiştir./ *Q-ZER N001(WHITE), N005(BLACK), N006(CHERRY), N007(ORANGE), N0011(PATTERNED)Mask model products are manufactured using fabric, elastic strap, nose clip, filter layer.*

Volkan AKIN
01.04.2022
Karar Verici / Approver

Okan AKEL
01.04.2022
Şirket Müdürü / General Manager

MNA Laboratuvarları San. Tic.Ltd .Şti
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CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT CHECK AT RANDOM INTERVALS (MODULE C2, ANNEX VII) (258-21-01-01)

Notified Body Number: 2841

Report No : 258-21-01-01

Report Date : 01.04.2022

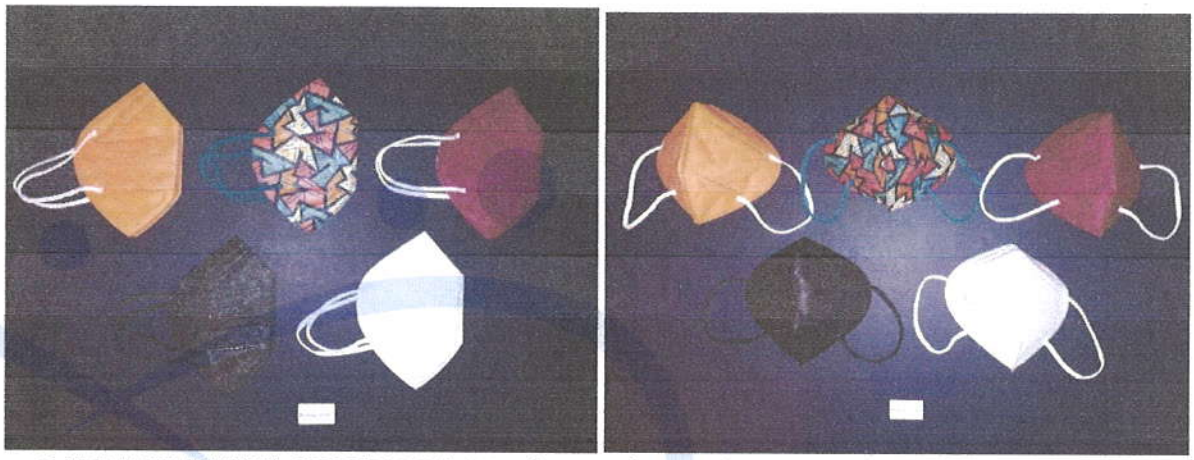
Application No : 258-21-01-01

1. **COMPANY INFORMATION:**
   PRİZMANET MEDİKAL SANAYİ TİCARET İTHALAT İHRACAT LİMİTED ŞİRKETİ
   Yahya Kemal Mah. Okul Cad. No:13/15, Kağıthane / İstanbul, TÜRKİYE
   Tel: +90 (212) 909 44 44
   E-mail: prizma@prizma.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**



Q-ZER N001(WHITE), N005(BLACK), N006(CHERRY), N007(ORANGE), N0011(PATTERNED)

5. **PPE DIMENSIONS:**
   Q-ZER N001(WHITE), N005(BLACK), N006(CHERRY), N007(ORANGE), N0011(PATTERNED) Mask model has been found to be produced using standard size.

6. **PPE PRODUCT MATERIAL INFORMATION:**
7.
   The product is made of elastic strap, nonwoven fabric on the outer and inner layers and fitler material on the middle layer.

8. **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.

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

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

Subject facial dimensions

Subject	Face Length (mm)	Face Width (mm)	Face Depth (mm)	Mouth Width (mm)
1	120	145	105	61
2	128	155	112	68
3	110	128	105	55
4	123	140	133	57
5	116	128	99	58
6	120	130	91	56
7	138	151	119	65
8	110	130	96	55
9	120	131	85	58
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 received	2,2	3,0
As received	2,5	2,8
As received	3,1	2,8
After the simulated wearing treatment	2,4	3,1
After the simulated wearing treatment	2,4	2,8
After the simulated wearing treatment	2,6	2,5
Mechanical strength and temperature conditioning (120 mg)	5,1	5,5
Mechanical strength and temperature conditioning (120 mg)	5,2	5,1
Mechanical strength and temperature conditioning (120 mg)	4,9	5,6

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	0,78 0,72 0,81	-	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	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 received	0,5	1,6
As received	0,5	1,6
As received	0,5	1,6
After temperature conditioning	0,4	1,5
After temperature conditioning	0,4	1,6
After temperature conditioning	0,4	1,6
After the simulated wearing treatment	0,5	1,5
After the simulated wearing treatment	0,4	1,5
After the simulated wearing treatment	0,4	1,5

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	2,7	2,6	2,6	2,6
As received	2,6	2,6	2,6	2,6	2,7
As received	2,7	2,7	2,7	2,7	2,7
After temperature conditioning	2,7	2,6	2,7	2,6	2,6
After temperature conditioning	2,6	2,6	2,6	2,6	2,6
After temperature conditioning	2,7	2,7	2,7	2,7	2,6
After the simulated wearing treatment	2,6	2,6	2,6	2,6	2,6
After the simulated wearing treatment	2,6	2,7	2,6	2,7	2,7
After the simulated wearing treatment	2,6	2,6	2,6	2,6	2,6

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
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

10. DECISION

Analysis and examinations Q-ZER N001(WHITE), N005(BLACK), N006(CHERRY), N007(ORANGE), N0011(PATTERNED) Mask 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.

11. ATTACHMENTS

- Basic Health Safety Requirements
- Risk Assessment
- Test Report (M-2022-0258, M-2022-0329)
- User Instruction

CONTROLLER : **VOLKAN AKIN**

SIGNATURE :

DATE : **01.04.2022**

MNA LABORATUVARI
ANALİZ RAPORU

Rapor Numarası : M-2022-0258	Tarih : 2022-04-01 18:36:30	Sayfa : 1 / 4	Rev:

Analizin Amacı	: Özel İstek
Numuneyi Gönd. Kuruluş	: PRİZMANET MEDİKAL SANAYİ TİCARET İTHALAT İHRACAT LİMİTED ŞİRKETİ
Adres	: YAHYA KEMAL MAHALLESİ OKUL CADDESİ NO: 13/15 KAĞITHANE/İSTANBUL
Numune Kabul Tarihi	: 2022-03-02 17:18:19
Analiz Tarihi	: 2022-03-02 17:59:55
Numune Miktarı	: 110 Adet
Numune Tanımı	: MEDİZER
Diğer Bilgiler	: MODULE C2

Solunum Direnci

Yapılan Analizler	Analiz Sonucu	Limit Değer	Method	Değerlendirme	Fiziksel Durum
Solunum Direnci	Check the table.	Check the table for limits	EN 149+A1 Madde 8.9	PASS (FFP2)	-

Inhalation	30 L/min		95 L/min	
As received	0,5		1,6	-0,5
After temperature conditioning	0,4		1,5	-0,4
After the simulated wearing treatment	0,5		1,5	-0,4
After the flow conditioning	-		-	--

Classification	30 L/min max basınç (mbar)	95 L/min max basınç (mbar)	160 L/min max basınç (mbar)
FFP1	0,6	2,1	3,0
FFP2	0,7	2,4	3,0
FFP3	1,0	3,0	3,0

Exhalation	Facing directly ahead		Facing vertically upwards	Facing vertically downwards		Lying on the left side		Lying on the right side	
As received	2,7		2,7	2,6	2,6		2,6		-2,6
After temperature conditioning	2,7		2,6	2,7	2,6		2,6		-2,6
After the simulated wearing treatment	2,6		2,6	2,6	2,6		2,6		-2,6
After the flow conditioning	-		-	-	-		-		--

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MNA LABORATUVARI
ANALİZ RAPORU

Rapor Numarası : M-2022-0258	Tarih : 2022-04-01 18:36:30	Sayfa : 3 / 4	Rev:

Yapılan Analizler	Analiz Sonucu	Limit Değer	Method	Değerlendirme	Fiziksel Durum
Solunan Havanın Karbondioksit Muhtevası Tayini	Check the table.	Maximum %1	EN 149+A1 Madde 8.7	PASS (FFP2)	-

	CO2 (%)
Sample 1	0,78
Sample 2	0,72
Sample 3	0,81

Filtre Malzemesinin Nüfuziyeti

Yapılan Analizler	Analiz Sonucu	Limit Değer	Method	Değerlendirme	Fiziksel Durum
Filtre Malzemesinin Nüfuziyeti	Check the table.	FFP1≤20 FFP2≤6 FFP3≤1	EN 149+A1 Madde 8.11, EN 13274-7	PASS (FFP2)	-

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

Alev Deneyi

Yapılan Analizler	Analiz Sonucu	Limit Değer	Method	Değerlendirme	Fiziksel Durum
Alev Deneyi	No flame seen.	Shall not burn for more than 5 sec after removal from the flame	EN 13274-4	PASS (FFP2)	-

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MNA LABORATUVARI
ANALİZ RAPORU

TÜRKAK
Test
TS EN ISO/IEC 17025
AB-1183-T

AB-1183-T
M-2022-0329
04-22

Rapor Numarası : M-2022-0329	Tarih : 2022-04-01 18:36:43	Sayfa : 1 / 3	Rev:

Analizin Amacı	: Özel İstek
Numuneyi Gönd. Kuruluş	: PRİZMANET MEDİKAL SANAYİ TİCARET İTHALAT İHRACAT LİMİTED ŞİRKETİ
Adres	: YAHYA KEMAL MAHALLESİ OKUL CADDESİ NO: 13/15 KAĞITHANE/İSTANBUL
Numune Kabul Tarihi	: 2022-04-01 14:22:29
Analiz Tarihi	: 2022-04-01 18:21:25
Numune Miktarı	: 80 Adet
Numune Tanımı	: MEDİZER
Diğer Bilgiler	:

Yasaklı Azo Boyar Maddelerin Tayini *

Yapılan Analizler	Analiz Sonucu	Limit Değer	Method	Değerlendirme	Fiziksel Durum
Yasaklı Azo Boyar Maddelerin Tayini	Check the table for results.	< 30 mg/kg	EN ISO 14362-1 / EN ISO 17234-1	PASS	-

CAS No	Substances
92-67-1	4-aminobiphenyl
92-87-5	Benzidine
95-69-2	4-chloro-o-toluidine
91-59-8	2-naphthylamine
97-56-3	o-aminoazotoluene
99-55-8	5-nitro-o-toluidine
106-47-8	4-chloroaniline
615-05-4	2,4-diaminoanisole
101-77-9	4,4-methylenedianiline
91-94-1	3,3-dichlorobenzidine
119-90-4	3,3-dimethoxybenzidine
119-93-7	3,3-dimethylbenzidine
838-88-0	4,4-methylenediotoluidine
120-71-8	p-cresidine
101-14-4	2,2-dichloro-4,4-methylene-dianiline
101-80-4	4,4-oxydianiline
139-65-1	4,4-thiodianiline
95-53-4	o-toluidine
95-80-7	2,4-diaminotoluene

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MNA LABORATUVARI
ANALİZ RAPORU

Test
TS EN ISO/IEC 17025
AB-1183-T

AB-1183-T
M-2022-0329
04-22

Rapor Numarası : M-2022-0329	Tarih : 2022-04-01 18:36:43	Sayfa : 3 / 3	Rev:

Deney laboratuvarı olarak faaliyet gösteren MNA Laboratuvarları, TÜRKAK 'tan AB-1183-T ile TS_EN_ISO/IEC_17025:2017 standardına göre akredite edilmiştir. Türk Akreditasyon Kurumu (TÜRKAK) deney raporlarının tanınırlığı konusunda Avrupa Akreditasyon Birliği (EA) ile çok taraflı anlaşma ve Uluslararası Laboratuvar Akreditasyon Birliği (ILAC) ile karşılıklı tanınma antlaşmasını imzalamıştır.

***Analiz akreditasyon kapsamındadır.**

Not :

1.Bu analiz raporunun hiçbir bölümü tek başına veya ayrı ayrı kullanılamaz ve laboratuvarın yazılı izni olmadan kısmen kopyalanıp çoğaltılamaz, üçüncü şahıslara ve reklam aracı olarak kullanılamaz.
2.Analiz sonuçları, MNA Laboratuvarları' na firma/kurum/şahıs tarafından gönderilen ve analiz edilen numune için geçerlidir. Bütünü temsil etmeyebilir.
3.İmzasız ve Mühürsüz raporlar geçersizdir.
4.Bu analiz raporu adli-idari işlemlerde ve reklam amacıyla kullanılamaz.
5.Sonuçlar numunenin teslim alındığı hali için geçerlidir.
6.Karar kuralı belirlenmiş bir spesifikasyona uygunluğu belirtirken, ölçüm belirsizliğinin nasıl hesaba katılacağını belirleyen kuraldır. TLM-052 Karar Kuralı Uygulama talimatına göre müşteri ile mutabık kalınarak seçilen karar kuralı gerekli olması durumunda uygulanacaktır.
7.Limit Değerleri analiz metotlarından alınarak belirlenmiştir.
8.Müşteri tarafından sağlanan bilgiler sonuçların geçerliliğini etkilemesi durumunda, laboratuvar sorumlu değildir.
9.Deney ve/veya ölçüm sonuçları, genişletilmiş ölçüm belirsizlikleri (olması halinde) ve deney metotları bu raporun tamamlayıcı kısmı olan takip eden sayfalarda verilmektedir.
10.Su geçirmezlik Tayini Hidrostatik Basınç Tayini TS ISO 811(Hidrostatik Basınç Tayini Cihazı E/N:53) Analizi, Dikiş Kopma Dayanımı EN ISO 13935-2 (Mukavemet Test Cihazı E/N:50) Analizi ve sıvı kimyasal geçirmeye dayanım TS EN 659-A1 Madde 3.18 (Sıvı Kimyasal Geçirme Cihazı E/N:107) analizi şartlandırma odasında gerçekleştirilmekte olup ortam şartları için ISO 139 MADDE 3.2 koşulları (23 ± 2° C sıcaklık ve %50 ± 4 bağıl nem) uygulanır.

Selin Gergin

Numune Kabul ve Raporlama Sorumlusu

2022-04-01 18:24:26

VOLKAN AKIN

Laboratuvar Müdürü

2022-04-01 18:35:48

Erhan Üstünel

Laboratuvar Sorumlusu

2022-04-01 18:26:55

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