

#### 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 DENETIMLI MUAYENESINE DAYALI TIPE UYCUNLUK

Belge No / Certificate No	: 48091178
Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /	1.100/11/0
Certification Date / Certificate Validity Date	: 25.10.2023-25.10.2024
Belge Geçerlilik Tarihi / Document Validity Period	: 1 vil / I vear
Firma Unvanı ve Adresi /	
Company Name and Address	: PHARMAPLAST S.A.E
Address-1: Amria free zone 23512, Alexandria Egypt.	
Address-2: Part number 2, block 7, third industrial zone	e, Borg el Arab, Alexandria, Egypt
Address-3: KRE LTD, "Pharmaplast group", Industrial	Area, 2830Katunsi, Sandanski, Bulgaria
Marka / Model / Brand / Model	: FS-F2E
Direktifi / Directive	: 2016/425 REGULATION
Modülü/Kategori / Module / Category	: C2 MODÜLÜ/ KATEGORÌ III

## Teknik Değerlendirme Rapor No/ Technical Evaluation Report No

MODULE C2 / CATEGORY III :48091178 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: FS-F2E model ürünleri kumaş, elastik kayış, burun klipsi ve filtre katmanı kullanılarak imal edilmiştir./ FS-F2E model products are manufactured using fabric, elastic strap, nose clip, filter layer,



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 Report No
 : 48091178

 Report Date
 : 25.10.2023

 Application No
 : 48091178

#### 1. COMPANY INFORMATION:

PHARMAPLAST S.A.E

Address-1: Amria free zone 23512, Alexandria Egypt. Address-2: Part number 2, block 7, third industrial zone, Borg el Arab, Alexandria, Egypt. Address-3: KRE LTD, "Pharmaplast group", Industrial Area, 2830Katunsi, Sandanski, Bulgaria.

#### 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



FS-F2E

5. PPE DIMENSIONS:

FS-F2E model has been found to be produced using standard size.

## 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.
- Suitable construction materials were determined by visual inspection according to EN 149:2001 +A1:2009.



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## 8. ANALYSIS EVALUATION AND MARKING:

EN 149:2001 +A1:2009

TESTS	TESTS PARAMETER PERFORMANCE LEVELS		RESULTS	PERFORMANC E LEVELS	EVALUATIO N		
		FFP1	FFP2	FFP3			
Part 7.3 Visual inspection	Shall also the man supplied by the man	king and th anufacture	ne infor	mation	Appropriate	•	PASS
Banned Azo Dyes	< 30 mg/kg				Not applicable		Not
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			offered hey are ge and	Appropriate	-	PASS
Part 7.5 Material	When conditioned in accordance 8.3.1 & 8.3.2 the particle filter half mask shall not collapse			3.3.1 & all not	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	17	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.			e into sharp	Appropriate	-	PASS

TESTS	PARAMETER	PERFORMANCE LEVELS		CE	RESULTS	PERFORMANCE EVALUATION	
		FFP1	FFP2	FFP3		5-73-97-7777-78-98	
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 Inwa	rd Leakage	(%)			
Alternation	Exercise 1	Exercise 2	Exercise 3	Exercise 4	Exercise 5	Average
Subject 1 (As received)	5,1	5,3	6,1	5,7	4,9	5.4
Subject 2 (As received)	4,9	4,8	4,6	3,9	4.0	4.4
Subject 3 (As received)	4,8	3,9	5,5	4.7	4.5	4.7
Subject 4 (As received)	3,5	3,6	4,4	3.2	2.7	3.5
Subject 5 (As received)	3,9	4.0	4.0	3.4	4.1	3.9
Subject 6 (After temperature conditioning)	5,8	5,4	6,3	5,1	5,5	5,6



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Subject 7 (After temperature conditioning)	3,4	2,9	2,8	2,9	3.1	3.0
Subject 8 (After temperature conditioning)	4,4	4,5	5.1	5.2	4.9	4.8
Subject 9 (After temperature conditioning)	4.6	3.8	4.2	3.8	3.7	4,0
Subject 10 (After temperature conditioning)	5,3	5,8	6,2	6.6	7.1	6.2

#### 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	PARAMETER	PERFO	ORMAN S	CE	RESULTS	PERFORMANCE	EVALUATION
		FFP1	FFP2	FFP3	-		
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	0,3	0.4
As received	0,2	0.3
As received	0,3	0,5
After the simulated wearing treatment	0,2	0.5
After the simulated wearing treatment	0,3	0.3
After the simulated wearing treatment	0,3	0.4
Mechanical strength and temperature conditioning (120mg)	1,2	2.0
Mechanical strength and temperature conditioning (120mg)	1,4	1.6
Mechanical strength and temperature conditioning (120mg)	1,1	2.1

TESTS PAR	PARAMETER	PERFORMANCE			RESULTS	PERFORMANCE	EVALUATION
		FFP1	FFP2	FFP3			
Part 7.10 Compatibility with skin	Materials shall no cause irritation or health	ot be know any other a	n to be adverse	likely to effect to	Appropriate	$\gamma$ ( (	PASS



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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	0,52 0,55 0,51	-	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	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	0,3	1,3
As received	0,4	1.3
As received	0,4	1.2
After temperature conditioning	0,3	1.2
After temperature conditioning	0,3	1.2
After temperature conditioning	0,3	1.2
After the simulated wearing treatment	0,4	1.3
After the simulated wearing treatment	0,3	1.2
After the simulated wearing treatment	0,3	1.2

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 received	2,1	2,1	2,0	2,1	2,1
As received	2,0	2,1	2,1	2,1	2.0
As received	2,1	2,1	2,1	2.0	2.1
After temperature conditioning	2,0	2,0	2,0	2,1	2.1
After temperature conditioning	2,1	2,0	2,1	2.1	2.0
After temperature conditioning	2,0	2,1	2,1	2,0	2.0
After the simulated wearing treatment	2,0	2,1	2,0	2.1	2.1
After the simulated wearing treatment	2,0	2,1	2,1	2.0	2.1
After the simulated wearing treatment	2,0	2,0	2,1	2,1	2.0

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TESTS	PARAMETER	PERFO	DRMAN .S	CE	RESULTS	PERFORMANCE	EVALUATION
		FFP1	FFP2	FFP3		000000000000	
Part 7.17 Clogging	After clogging the inhalation resistances shall not exceed. (valved)	4 mba r	5 mba r	7 mbar	Not applicable	-	Not applicable
	The exhalation resist 3 mbar at 160 L/ ( (valved)	tance sł min co	nall not ntinuou	exceed s flow.	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	20 20	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	

#### 9. ATTACHMENTS

Test Reports (M-2023-0575)

:

CONTROLLER

SIGNATURE

DATE

: VOLKAN AKIN : 25.10.2023





Report Nu. : M-2023-0575	Date : 2023-10-25 14:41:37	Page : 1 / 6	Rev:
Purpose of Analysis	: Special request		
Sample Send Org.	: Pharmaplast SAE		
Address	: Amria Free Zone, 23512, .	Akexandria, Egypt	
Sample Acceptance Date	: 2023-09-20 08:16:34		
Analysis Date	: 2023-09-20 13:39:57		
Sample Quantity	: 120 Pieces		
Sample Description	: Pharmaplast FS-F2E		
Other informations	:		

Tests	Evaluation	
Flammability	PASS	
Penetration Of Filter Material	PASS (FFP2)	
Carbon Dioxide Content Of The Inhalation Air	PASS (FFP2)	
Breathing Resistance	PASS (FFP2)	
Total Inward Leakage	PASS (FFP2)	

## Flammability

Device: Flammability tester

Measurement uncertainty:-

Tests	Analysis result	Limit Value	Method	Evaluation	Physical Condition
Flammability	No flame seen	Shall not burn for more than 5 sec after removal from the flame	EN 13274-4	PASS	-

# **Penetration Of Filter Material**

**Device:Filter Test System** 

#### Measurement uncertainty:±0,080

Tests	Analysis result	Limit Value	Method	Evaluation	Physical Condition
Penetration Of Filter Material	Check the table	FFP1≤20 FFP2≤6 FFP3≤1	EN 149+A1 Part 8.11, EN 13274-7	PASS (FFP2)	-



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

## **Carbon Dioxide Content Of The Inhalation Air**

Device:Carbon DioxideTester

Measurement uncertainty:±0,072

Tests	Analysis result	Limit Value	Method	Evaluation	Physical Condition
Carbon Dioxide Content Of The Inhalation Air	Check the table	Maximum %1	EN 149+A1 Part 8.7	PASS (FFP2)	-

	CO2 (%)
Sample 1	0,52
Sample 2	0,55
Sample 3	0,51

## **Breathing Resistance**

Device:Breathing Resistance Tester

Measurement uncertainty: Inhalation 30L/min:±0,160,Inhalation30 L/min:±0,026 Exhalation 160 L/min:0,046

Tests	Analysis result	Limit Value	Method	Evaluation	Physical Condition

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# MNA LABORATORY ANALYSIS REPORT

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Breathing Resistance	Check tl	ne table	See the limits table.	EN 149+A1 Part 8.9	PASS	(FFP2)	-

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

Inhalation	30 L/min	95 L/min			
As received 1	0,3	1,3			
As received 2	0,4	1,3			
As received 3	0,4	1,2			
After temperature conditioning 1	0,3	1,2			
After temperature conditioning 2	0,3	1,2			
After temperature conditioning 3	0,3	1,2			
After the simulated wearing treatment 1	0,4	1,3			
After the simulated wearing treatment 2	0,3	1,2			
After the simulated wearing treatment 3	0,3	1,2			
After the flow conditioning 1	-	-			
After the flow conditioning 2	-	-			
After the flow conditioning 3					

Exhalation 160L/min	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	2,0	2,1	2,1
As received 2	2,0	2,1	2,1	2,1	2,0
As received 3	2,1	2,1	2,1	2,0	2,1
After temperature conditioning 1	2,0	2,0	2,0	2,1	2,1
After temperature conditioning 2	2,1	2,0	2,1	2,1	2,0
After temperature conditioning 3	2,0	2,1	2,1	2,0	2,0
After the simulated wearing treatment 1	2,0	2,1	2,0	2,1	2,1
After the simulated wearing treatment 2	2,0	2,1	2,1	2,0	2,1
After the simulated wearing treatment 3	2,0	2,0	2,1	2,1	2,0



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After the flow - conditioning 1	-	-	-	-	
After the flow - conditioning 2	-	-	-	-	
After the flow conditioning 3					

## **Total Inward Leakage**

Device: Total Inward Leakage Tester

Measurement uncertainty:±0,090

Tests	Analysis result	Limit Value	Method	Evaluation	Physical Condition
Total Inward Leakage	Check the table	See the limits table.	EN 149+A1 Part 8.5	PASS (FFP2)	-

	At least 46 out of the 50 individual exercise result shall be not greater than	At least 8 out of the 10 individual wearer arithmetic means shall be not greater than
FFP1	≤25	≤22
FFP2	≤11	≤8
FFP3	≤5	≤2

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



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Subject 10 (After temperature conditioning)	5,3	5,8	6,2	6,6	7,1		6,2

# MNAL/ MNA LABORATORY ANALYSIS REPORT

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Operating as a test laboratory, MNA Laboratories is accredited by TÜRKAK according to AB-1183-T and TS\_EN\_ISO/IEC\_17025:2017 standards has been done. A signed a mutual recognition agreement with the International Laboratory Accreditation Association (ILAC).

\*The analysis is within the scope of accreditation.

Note :

1. No part of this analysis report may be used alone or separately and may be partially copied or reproduced without the written permission of the laboratory. It cannot be reproduced, used by third parties or as a means of advertising.

2. Analysis results are valid for the sample sent and analyzed by the company/institution/individual to MNA Laboratories. represent the whole may not. 3. Unsigned and Unsealed reports are invalid.

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5. Results are valid for the sample received.

6. The decision rule is the rule that determines how measurement uncertainty is taken into account when specifying compliance with an established specification. The customer may choose to apply and/or not apply the decision rule (except in cases where legislation/standards are mandatory). If the customer prefers to apply the decision rule; According to the TLM-052 Decision Rule Application instruction published on the www.mnalab.com website, the decision rule selected in agreement is applied and reported by stating the relevant analysis and decision rule method in the "Note" section. If the customer leaves the decision rule application to the laboratory's evaluation, MNA LABORATORIES applies the simple decision rule. 7. Limit Values are determined by taking from analysis methods.

8. The laboratory is not responsible if the information provided by the CUSTOMER affects the validity of the results.

9. Test and / or measurement results, expanded measurement uncertainties (if any) and test methods are given in the following pa ges, which are the supplementary part of this certificate.

. 10. Water Repellency Determination Hydrostatic Pressure Determination T S ISO 811 (Hydrostatic Pressure Tester E / N: 53) Analysis, Seam Strength EN ISO 13935-2 (Strength Test Device E / N: 50) Analysis and resistance to liquid chemical permeation TS EN 659 -A1 Part 3.18 (Liquid Chemical Transfer Device E / N: 107) Analysis is carried out in the conditioning room and ISO 139 PART 3.2 conditions (23 ± 2 ° C temperature and 50 ± 4% relative humidity) are applied for ambient conditions.

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Sample Acceptance and Reporting Officer

2023-10-25 14:41:19

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VOLKAN AKIN Laboratory Manager 2023-10-25 14:34:43

Erhan Üstünel Laboratory Responsible 2023-10-25 14:34:02

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