MNA LABORATUVARLARI
Notify Body No: 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* : 57091116
Belgelendirme Tarihi - Bir Sonraki Belge Tarihi / *Certification Date / Certificate Validity Date* : 27.11.2023-27.11.2024
Belge Geçerlilik Tarihi / *Document Validity Period* : 1 yıl / *1 year*
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, Borg el Arab, Alexandria, Egypt.
Address-3: KRE LTD, "Pharmaplast group", Industrial Area, 2830Katunsi, Sandanski, Bulgaria.
Marka / Model / *Brand / Model* : FC-F2H
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* : 57091116
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*: FC-F2H model ürünleri kumaş, elastik kayış, burun klipsi ve filtre katmanı kullanılarak imal edilmiştir./ FC-F2H *model products are manufactured using fabric, elastic strap, nose clip, filter layer.*

Karar Verici / Approver ***Şirket Müdürü / General manager***

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Date: 2023.11.27 09:10:19 +03'00'

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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) (57091116)

Report No : 57091116

Report Date : 27.11.2023

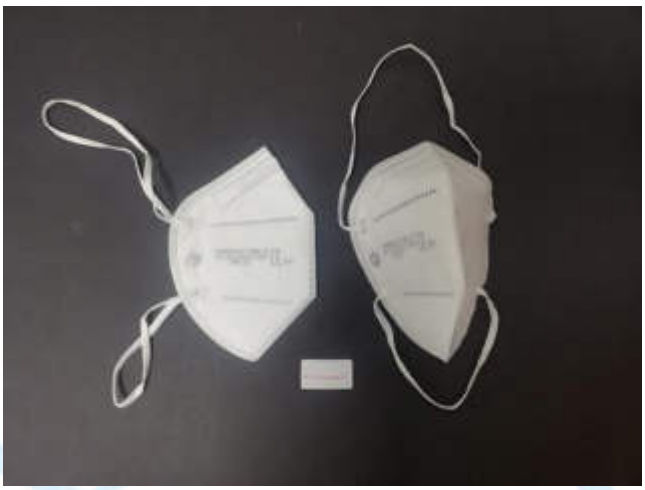
Application No : 57091116

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**



FC-F2H

5. **PPE DIMENSIONS:**
   FC-F2H 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.

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	< 30 mg/kg				Not applicable	-	Not applicable
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)	4,9	5,1	5,0	5,5	4,7	5,0
Subject 2 (As received)	4,7	4,6	4,4	5,9	3,8	4,7
Subject 3 (As received)	4,6	3,7	5,3	4,5	4,3	4,5

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

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	0,8	1,0
As received	0,9	0,8
As received	0,7	0,9
After the simulated wearing treatment	0,6	0,9
After the simulated wearing treatment	0,9	0,9
After the simulated wearing treatment	0,8	1,0
Mechanical strength and temperature conditioning (120mg)	4,0	4,1
Mechanical strength and temperature conditioning (120mg)	4,1	4,3
Mechanical strength and temperature conditioning (120mg)	4,2	4,3

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				0,55 0,50 0,52	-	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	1,7
As received	0,4	1,6
As received	0,5	1,6
After temperature conditioning	0,5	1,6
After temperature conditioning	0,5	1,6
After temperature conditioning	0,5	1,7
After the simulated wearing treatment	0,4	1,6
After the simulated wearing treatment	0,4	1,6
After the simulated wearing treatment	0,4	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	2,8	2,8	2,7	2,7	2,8
As received	2,8	2,7	2,8	2,7	2,8
As received	2,8	2,8	2,7	2,7	2,7
After temperature conditioning	2,8	2,7	2,8	2,7	2,8
After temperature conditioning	2,7	2,8	2,7	2,8	2,8
After temperature conditioning	2,8	2,7	2,7	2,7	2,8
After the simulated wearing treatment	2,7	2,7	2,7	2,8	2,7
After the simulated wearing treatment	2,8	2,7	2,7	2,7	2,7
After the simulated wearing treatment	2,7	2,7	2,7	2,8	2,7

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

9. ATTACHMENTS

- Test Reports (M-2023-0574)

CONTROLLER :

SIGNATURE : Digitally signed by VOLKAN AKIN
Date: 2023.11.27 09:08:37 +03'00'

DATE :

MNA LABORATORY
ANALYSIS REPORT

Report Nu. : M-2023-0574	Date : 2023-11-07 13:42:12	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 08:15:24
Analysis Date	: 2023-09-20 13:40:49
Sample Quantity	: 120 Pieces
Sample Description	: Pharmaplast FC-F2H
Other informations	:

Tests	Method	Expected performance level	Evaluation
Penetration Of Filter Material	**EN 149+A1 Part 8.11, EN 13274-7**	**-**	**PASS (FFP2)**
Flammability	**EN 13274-4**	**-**	**PASS**
Breathing Resistance	**EN 149+A1 Part 8.9**	**-**	**PASS (FFP2)**
Carbon Dioxide Content Of The Inhalation Air	**EN 149+A1 Part 8.7**	**-**	**PASS**
Total Inward Leakage	**EN 149+A1 Part 8.5**	**-**	**PASS (FFP2)**

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)**	**-**

	Sodium Chloride (%)	Paraffin Oil (%)
As received 1	**0,8**	**1,0**
As received 2	**0,9**	**0,8**
As received 3	**0,7**	**0,9**
After the simulated wearing treatment 1	**0,6**	**0,9**
After the simulated wearing treatment 2	**0,9**	**0,9**
After the simulated wearing treatment 3	**0,8**	**1,0**
Mechanical strength and temperature conditioning (120 mg) 1	**4,0**	**4,1**

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Mechanical strength and temperature conditioning (120 mg) 2	**4,1**	**4,3**
Mechanical strength and temperature conditioning (120 mg) 3	**4,2**	**4,3**

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**	**-**

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
Breathing Resistance	**Check the 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	**0,5**	**1,7**
As received 2	**0,4**	**1,6**
As received 3	**0,5**	**1,6**
After temperature conditioning 1	**0,5**	**1,6**
After temperature conditioning 2	**0,5**	**1,6**
After temperature conditioning 3	**0,5**	**1,7**
After the simulated wearing treatment 1	**0,4**	**1,6**

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After the simulated wearing treatment 2	**0,4**	**1,6**
After the simulated wearing treatment 3	**0,4**	**1,7**
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	**2,8**	**2,8**	**2,7**	**2,7**	**2,8**
As received 2	**2,8**	**2,7**	**2,8**	**2,7**	**2,8**
As received 3	**2,8**	**2,8**	**2,7**	**2,7**	**2,7**
After temperature conditioning 1	**2,8**	**2,7**	**2,8**	**2,7**	**2,8**
After temperature conditioning 2	**2,7**	**2,8**	**2,7**	**2,8**	**2,8**
After temperature conditioning 3	**2,8**	**2,7**	**2,7**	**2,7**	**2,8**
After the simulated wearing treatment 1	**2,7**	**2,7**	**2,7**	**2,8**	**2,7**
After the simulated wearing treatment 2	**2,8**	**2,7**	**2,7**	**2,7**	**2,7**
After the simulated wearing treatment 3	**2,7**	**2,7**	**2,7**	**2,8**	**2,7**
After the flow conditioning 1	**-**	**-**	**-**	**-**	**-**
After the flow conditioning 2	**-**	**-**	**-**	**-**	**-**
After the flow conditioning 3					

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**	**-**

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MNA LABORATORY
ANALYSIS REPORT

Report Nu. : M-2023-0574	Date : 2023-11-07 13:42:12	Page : 4 / 6	Rev:

	CO2 (%)
Sample 1	**0,55**
Sample 2	**0,50**
Sample 3	**0,52**

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

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Report Nu. : M-2023-0574	Date : 2023-11-07 13:42:12	Page : 5 / 6	Rev:

Subject 10 (After temperature conditioning)	**5,1**	**4,7**	**5,1**	**3,9**	**5,2**	**4,8**

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ANALYSIS REPORT

Report Nu. : M-2023-0574	Date : 2023-11-07 13:42:12	Page : 6 / 6	Rev:

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 multilateral agreement with the European Accreditation Association (EA) on the recognition of the Turkish Accreditation Agency (TÜRKAK) test reports and It has 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.

4.This analysis report cannot be used in judicial-administrative proceedings or for advertising purposes.
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.

Selin Gergin

Sample Acceptance and Reporting Officer

2023-11-07 13:41:55

VOLKAN AKIN

Laboratory Manager

2023-11-07 13:41:24

Erhan Üstünel

Laboratory Responsible

2023-11-07 13:40:48

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