

#### 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 / Model / Brand / Model Direktifi / Directive Modülü/Kategori / Module / Category

Teknik Değerlendirme Rapor No/ Technical Evaluation Report No Ürün Tipi / Product Type:

#### : 57071722

: 18.09.2023-18.09.2024

: 1 yıl / 1 year

: Fit Pharm Technologies GmbH Industriestraße 45, 48629 Metelen Deutschland : FIT F262

- : 2016/425 REGULATION
- : C2 MODÜLÜ/ KATEGORİ III MODULE C2 / CATEGORY III

: MNA 57071722

 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: FIT F262 model ürünleri kumaş, elastik kayış, burun klipsi ve filtre katmanı kullanılarak imal edilmiştir. / FIT F262 model products are manufactured using fabric, elastic strap, nose clip, filter layer.



MNA Laboratuvarları San. Tic.Ltd .Şti Adres: Küçükbakkalköy Mahallesi Yenidoğan Cad.No:21 Ataşehir/ İstanbul Tel: 0216 574 07 08 Faks: 0216 575 13 31 <u>www.mnalab.com</u>



U-Form-002/Rev.06/25.04.2022



## CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT CHECK AT RANDOM INTERVALS (MODULE C2, ANNEX VII) (57071722)

Report No	: 57071722
Report Date	: 18.09.2023

Application No : 57071722

 COMPANY INFORMATION: Fit Pharm Technologies GmbH Industriestraße 45, 48629 Metelen Deutschland

#### 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



FIT F262 (NAVY BLUE-MEDICAL GREEN-NUDE PINK-YELLOW-WHITE)

#### 5. PPE DIMENSIONS:

FIT F262 model has been found to be produced using small 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	PERFC LEVEL	1	ICE	RESULTS	PERFORMAN CE LEVELS	EVALUATIO
		FFP1	FFP 2	FFP3			



## (MODULE C2, ANNEX VII) (57071722)

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	2	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			E RESULTS PERFORMANC EVALUE E LEVELS			EVALUATION
		FFP1	FFP 2	FFP3		al market and		
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	(%)			
	Exercise 1	Exercise 2	Exercise 3	Exercise 4	Exercise 5	Average
Subject 1 (As received)	2,8	3,3	4,2	5,9	5,8	4.4
Subject 2 (As received)	7,8	9,5	9,6	8,1	8,2	8,6
Subject 3 (As received)	2,4	3,3	7,1	6.5	3,9	4,6
Subject 4 (As received)	4.1	4,3	3,6	7,2	3,0	4,4
Subject 5 (As received)	3.0	3,5	5,5	7,3	5,9	5,0
Subject 6 (After temperature conditioning)	3,2	3,7	7,4	5,3	4,2	4,8
Subject 7 (After temperature conditioning)	3,2	4,1	7,8	8,7	8,4	6,4
Subject 8 (After temperature conditioning)	4,9	5,8	5,7	7,4	5,9	5,9
Subject 9 (After temperature conditioning)	4.3	4,6	2,8	4.6	4,0	4,1
Subject 10 (After temperature conditioning)	2,9	3,2	4,6	6,5	4,9	4,4

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

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## (MODULE C2, ANNEX VII) (57071722)

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	PERF	ORMAI	NCE	RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP 1	FFP 2	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	1,9	3,2
As received	1,8	3,6
As received	1.6	3,8
After the simulated wearing treatment	1.7	3,0
After the simulated wearing treatment	1,5	3,4
After the simulated wearing treatment	1,8	3,1
Mechanical strength and temperature conditioning (120mg)	4,1	5,2
Mechanical strength and temperature conditioning (120mg)	3,5	5,5
Mechanical strength and temperature conditioning (120mg)	4,0	5,3

TESTS	PARAMETER	PERF	ORMAN _S	ICE	RESULTS	PERFORMANC E LEVELS	EVALUATIO N
		FFP1	FFP 2	FFP3			
Part 7.10 Compatibility with skin	Materials shall not b cause irritation or an health				Appropriate	्ता.	PASS
Part 7.11 Flammibility	Mask shall not burn of for more than 5 s	or not to	continu	ie to burn	Flame not seen	2	PASS
Part 7.12 Carbondioxide content of the inhalation air	Shall not exceed an a	verage c	of % 1		0,50 0,55 0,51		PASS
Part 7.13 Head harness	It can be donned and	removed	l easily	5	Appropriate	1	PASS
Part 7.14 Field of vision	The field of vision sha performance test.	all accep	table in	practical	Appropriate	-	PASS
Part 7.15 Exhalation valve(s)	It shall withstand axia apply for 10 s. If fitted, shall continue a continuous exhalation a period of 30 s.	to opera	ate corre	ectly after	Not applicable		Not applicable



Notified Body Number: 2841

## (MODULE C2, ANNEX VII) (57071722)

TESTS	PARAMETER	PERFORMANCE LEVELS		RESULTS	PERFORMANC E LEVELS	EVALUATIO	
		FFP1	FFP 2	FFP3			×020
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	0.4	1,7	
As received	0,5	1.7	
As received	0,5	1,6	
After temperature conditioning	0,5	1,5	
After temperature conditioning	0,4	1,5	
After temperature conditioning	0.4	1,4	
After the simulated wearing treatment	0,5	1,6	
After the simulated wearing treatment	0,4	1,6	
After the simulated wearing treatment	0,4	1,6	

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	2,4	2,4	2,4	2,3	2,4
As received	2,3	2,3	2,3	2,4	2,4
As received	2,3	2,4	2,4	2,3	2,4
After temperature conditioning	2,1	2,1	2.0	2,0	2,1
After temperature conditioning	2,2	2,1	2,1	2,1	2,2
After temperature conditioning	2,1	2,1	2,0	2,0	2,0
After the simulated wearing treatment	2,3	2,4	2,4	2,3	2.4
After the simulated wearing treatment	2,4	2,4	2,3	2,3	2,3
After the simulated wearing treatment	2,4	2,3	2,3	2,3	2,4

TESTS	ESTS PARAMETER PERFORMANCE RESULTS LEVELS	RESULTS	PERFORMANCE	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	Not applicable	-	Not applicable
The exhalation resistance sha mbar at 160 L/ min continuou				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 par readily connected possible by hand.		itted) si secured		Not applicable	$\gamma$ ( /	Not applicable
Part 9 Marking	The packaging information shall be clearly and durably marked on the smallest			Appropriate	*	PASS	



## (MODULE C2, ANNEX VII) (57071722)

commercially available packaging or legible	
through it if the packaging is transparent.	

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- 9. ATTACHMENTS
- Test Reports (M-2023-0511, M-2023-0512)

: VOLKAN AKIN CONTROLLER

SIGNATURE

:

DATE

: 18.09.2023



Report Nu. : M-2023-0511	Date : 2023-09-13 11:28:21	Page : 1 / 5	Rev:		
Purpose of Analysis	: Special request	: Special request			
Sample Send Org.	: FIT Pharm Technologies	: FIT Pharm Technologies GmbH			
Address	: Industriestr. 45, 48629 M	: Industriestr. 45, 48629 Metelen			
Sample Acceptance Date	: 2023-08-24 15:57:17	: 2023-08-24 15:57:17			
Analysis Date	: 2023-08-25 09:44:47	: 2023-08-25 09:44:47			
Sample Quantity	: 120 Pieces	: 120 Pieces			
Sample Description	: FIT F262	: FIT F262			
Other informations	:	:			

### 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)	-

	Sodium Chloride (%)	Paraffin Oil (%)
As received 1	1,9	3,2
As received 2	1,8	3,6
As received 3	1,6	3,8
After the simulated wearing treatment 1	1,7	3,0
After the simulated wearing treatment 2	1,5	3,4
After the simulated wearing treatment 3	1,8	3,1
Mechanical strength and temperature conditioning (120 mg) 1	4,1	5,2



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Mechanical strength and temperature conditioning (120 mg) 2		3,5		5,5	
Mechanical strength and temperature conditioning (120 mg) 3		4,0		5,3	

### **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	-

	CO2 (%)
Sample 1	0,50
Sample 2	0,55
Sample 3	0,51

### **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)	2,8	3,3	4,2	5,9	5,8	4,4

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

## **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	0,4	1,7
As received 2	0,5	1,7
As received 3	0,5	1,6

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After temperature conditioning 1		0,5		1,5	
After temperature conditioning 2		0,4		1,5	
After temperature conditioning 3		0,4		1,4	
After the simulated wearing treatment 1		0,5		1,6	
After the simulated wearing treatment 2		0,4		1,6	
After the simulated wearing treatment 3		0,4		1,6	
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	2,4	2,4	2,4	2,3	2,4
As received 2	2,3	2,3	2,3	2,4	2,4
As received 3	2,3	2,4	2,4	2,3	2,4
After temperature conditioning 1	2,1	2,1	2,0	2,0	2,1
After temperature conditioning 2	2,2	2,1	2,1	2,1	2,2
After temperature conditioning 3	2,1	2,1	2,0	2,0	2,0
After the simulated wearing treatment 1	2,3	2,4	2,4	2,3	2,4
After the simulated wearing treatment 2	2,4	2,4	2,3	2,3	2,3
After the simulated wearing treatment 3	2,4	2,3	2,3	2,3	2,4
After the flow conditioning 1	-	-	-	-	-
After the flow conditioning 2	-	-	-	-	-
After the flow conditioni	After the flow conditioning 3				



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\*The analysis is within the scope of accreditation.

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6. A decision rule is a rule that determines how measurement uncertainty is to be taken into account when specifying compliance with a specified specification.TLM-052 Decision Rule According to the implementation instruction, the decision rule chosen in agreement with the customer will be applied if necessary.

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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 13965-2

10. Water Repellency Determination Hydrostatic Pressure Determination T S ISO 811 (Hydrostatic Pressure Tester E / N: 53) Analysis, Seam Strength EN ISO 13965-2 (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

2023-09-13 11:26:42

Erhan Üstünel Laboratory Responsible 2023-09-13 11:16:18

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VOLKAN AKIN Laboratory Manager 2023-09-13 11:20:12

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## ANALYSIS REPORT



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M-2023-0512

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Report Nu. : M-2023-0512	Date : 2023-09-13 11:28:43	Page : 1 / 3	Rev:		
Purpose of Analysis	: Special request				
Sample Send Org.	: FIT Pharm Technologies	: FIT Pharm Technologies GmbH			
Address	: Industriestr. 45, 48629 I	: Industriestr. 45, 48629 Metelen			
Sample Acceptance Date	: 2023-08-24 16:03:12	: 2023-08-24 16:03:12			
Analysis Date	: 2023-08-25 09:45:02	: 2023-08-25 09:45:02			
Sample Quantity	: 25 Pieces	: 25 Pieces			
Sample Description	: FIT F262	: FIT F262			
Other informations	:				

## Banned Azo Dyes \*

Device:GC-MS

Measurement uncertainty: Textile:±0,350 Leather:±0,390

Tests	Analysis result	Limit Value	Method	Evaluation	Physical Condition
Banned Azo Dyes	Check the table for results.	≤30 mg/kg	EN ISO 14362-1 / EN ISO 17234-1	PASS	-

Part of Sample	Results(mg/kg)
Navy Blue+Yellow+Nude Pink,Medical Green	<5

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

## MNA LABORATORY ANALYSIS REPORT



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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		
137-17-7		2,4,5-trimethylaniline		
90-04-0		o-anisidine		
60-09-3		4-aminoazobenzene		

# MNALABS

## MNA LABORATORY ANALYSIS REPORT



АВ-1183-Т

M-2023-0512

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10. Water Repellency Determination Hydrostatic Pressure Determination T S ISO 811 (Hydrostatic Pressure Tester E / N: 53) Analysis, Seam Strength EN ISO 13965-2 (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

2023-08-25 18:26:13

Erhan Üstünel Laboratory Responsible 2023-08-25 18:27:25

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VOLKAN AKIN Laboratory Manager 2023-08-25 18:24:15