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*	: 77-20-01-02
Belgelendirme Tarihi - Bir Sonraki Belge Tarihi / *Certification Date / Certificate Validity Date*	: 29.07.2022-29.07.2023
Belge Geçerlilik Tarihi / *Document Validity Period*	: 1 yıl / *1 year*
Firma Unvanı ve Adresi / *Company Name and Address*	: Fit Pharm Technologies GmbH Benzstraße 13 48619 Heek Nordrhein-Westfalen Deutschland
Marka / Model / *Brand / Model*	: FIT F260
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*	: 77-20-01-02

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*: FIT F260 model ürünleri kumaş, elastik kayış, burun klipsi ve filtre katmanı kullanılarak imal edilmiştir./ FIT F260 *model products are manufactured using fabric, elastic strap, nose clip, filter layer.*

Faruk SARIHAN
29.07.2022
Karar Verici / Approver

Okan AKEL
29.07.2022
Şirket Müdürü / General manager

Notified Body Number: 2841

CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT CHECK AT RANDOM INTERVALS (MODULE C2, ANNEX VII) (77-20-01-02)

Report No : 77-20-01-02

Report Date : 25.07.2022

Application No : 77-20-01-02

1. **COMPANY INFORMATION:**

Fit Pharm Technologies GmbH
Benzstraße 13 48619 Heek Nordrhein-Westfalen Deutschland
Tel: +491605319004
E-mail: s.babitzki@farm-innovation-team.de

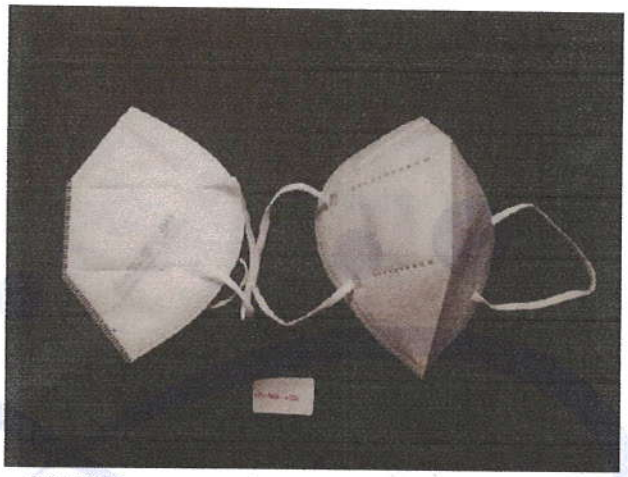
2. **PPE INFORMATION:**

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**



FIT F260

5. **PPE DIMENSIONS:**

FIT F260 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	FFP3	PASS
	At least 8 out of the 10 individual wearer arithmetic means	≤22	≤8	≤2	See the table below	FFP3	PASS

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

Subject 7 (After temperature conditioning)	1,0	1,0	1,3	1,4	1,6	1,3
Subject 8 (After temperature conditioning)	0,9	0,9	1,5	1,6	1,3	1,2
Subject 9 (After temperature conditioning)	1,9	1,6	1,2	1,5	1.6	1.6
Subject 10 (After temperature conditioning)	1,2	0,9	0,9	1,3	1,2	1,1

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	FFP3	PASS
	Paraffin oil, 95 L/min %, max	% 20	% 6	% 1	See the table below	FFP3	PASS

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

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	0,82 0,85 0,80	-	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	FFP3	PASS
	Inhalation 95L/min	2,1 mbar	2,4 mbar	3,0 mbar	See the table below	FFP3	PASS
	Exhalation 160L/min	3,0 mbar	3,0 mbar	3,0 mbar	See the table below	FFP3	PASS

Breathing Resistance (mbar)	Inhalation 30L/min	Inhalation 95L/min
As received	0,7	2,2
As received	0,8	2,1
As received	0,8	2,1
After temperature conditioning	0,7	2,0
After temperature conditioning	0,7	2,1
After temperature conditioning	0,8	2,0
After the simulated wearing treatment	0,6	2,0
After the simulated wearing treatment	0,6	2,0
After the simulated wearing treatment	0,7	2,0

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	2,9	2,7	2,7
As received	2,8	2,8	2,9	2,7	2,9
As received	2,8	2,8	2,7	2,8	2,9
After temperature conditioning	2,8	2,7	2,8	2,7	2,7
After temperature conditioning	2,7	2,7	2,7	2,7	2,7

After temperature conditioning	2,8	2,8	2,8	2,8	2,7
After the simulated wearing treatment	2,4	2,3	2,3	2,4	2,3
After the simulated wearing treatment	2,3	2,4	2,3	2,4	2,3
After the simulated wearing treatment	2,3	2,3	2,3	2,3	2,4

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. DECISION

Analysis and examinations FIT F260 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.

10. ATTACHMENTS

- Basic Health Safety Requirements
- Risk Assessment
- Test Reports (M-2022-0321)
- User Instruction

CONTROLLER : **FARUK SARIHAN**

SIGNATURE :

DATE : **25.07.2022**

MNA LABORATORY
ANALYSIS REPORT

Report Nu. : M-2022-0321	Date : 2022-06-18 12:28:03	Page : 1 / 5	Rev:

Purpose of Analysis	: Special request
Sample Send Org.	: FIT Pharm Technologies GmbH
Address	: Benzstr. 13
Sample Acceptance Date	: 2022-03-31 16:56:54
Analysis Date	: 2022-03-31 17:02:40
Sample Quantity	: 80 Pieces
Sample Description	: F260
Other informations	:

Flammability

Tests	Analysis result	Limit Value	Method	Evaluation	Physical Condition
Flammability	**Check the table for results.**	**Shall not burn for more than 5 sec after removal from the flame**	**EN 13274-4**	**PASS**	**-**

Penetration Of Filter Material

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

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

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ANALYSIS REPORT

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Carbon Dioxide Content Of The Inhalation Air

Tests	Analysis result	Limit Value	Method	Evaluation	Physical Condition
Carbon Dioxide Content Of The Inhalation Air	Check the table for results.	Maximum %1	EN 149+A1 Part 8.7	PASS(FFP3)	-

	CO2 (%)
Sample 1	0,82
Sample 2	0,85
Sample 3	0,80

Breathing Resistance

Tests	Analysis result	Limit Value	Method	Evaluation	Physical Condition
Breathing Resistance	Check the table for results.	Check the table for limits	EN 149+A1 Part 8.9	PASS(FFP3)	-

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

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After the flow conditioning 2	**-**	**-**
After the flow conditioning 3	**-**	**-**

Exhalation	Facing directly ahead	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side
As received 1	**2,7**	**2,7**	**2,9**	**2,7**	**2,7**
As received 2	**2,8**	**2,8**	**2,9**	**2,7**	**2,9**
As received 3	**2,8**	**2,8**	**2,7**	**2,8**	**2,9**
After temperature conditioning 1	**2,8**	**2,7**	**2,8**	**2,7**	**2,7**
After temperature conditioning 2	**2,7**	**2,7**	**2,7**	**2,7**	**2,7**
After temperature conditioning 3	**2,8**	**2,8**	**2,8**	**2,8**	**2,7**
After the simulated wearing treatment 1	**2,4**	**2,3**	**2,3**	**2,4**	**2,3**
After the simulated wearing treatment 2	**2,3**	**2,4**	**2,3**	**2,4**	**2,3**
After the simulated wearing treatment 3	**2,3**	**2,3**	**2,3**	**2,3**	**2,4**
After the flow conditioning 1	**-**	**-**	**-**	**-**	**-**
After the flow conditioning 2	**-**	**-**	**-**	**-**	**-**
After the flow conditioning 3	**-**	**-**	**-**	**-**	**-**

Total Inward Leakage

Tests	Analysis result	Limit Value	Method	Evaluation	Physical Condition
Total Inward Leakage	**Check the table for results.**	**Check the table for limits**	**EN 149+A1 Part 8.5**	**PASS(FFP3)**	**-**

	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**

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

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***The analysis is within the scope of accreditation.**

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3. Unsigned and Unsealed reports are invalid.
4. This analysis report cannot be used in judicial-administrative proceedings and for advertising purposes.
5. Results are valid for the sample received.
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.
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 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

2022-06-18 12:27:51

Erhan Üstünel

Laboratuvar Sorumlusu

2022-06-17 17:49:38

VOLKAN AKIN

Laboratuvar Müdürü

2022-06-18 11:47:15

FRM:23/rev.02/09.08.2019