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MNA LABORATUVARLARI

TECHNICAL EVALUATION REPORT

Report No

: M-2020-00446

Report Date

: 16.11.2020

1. COMPANY INFORMATION:

Fit Pharm Technologies GmbH

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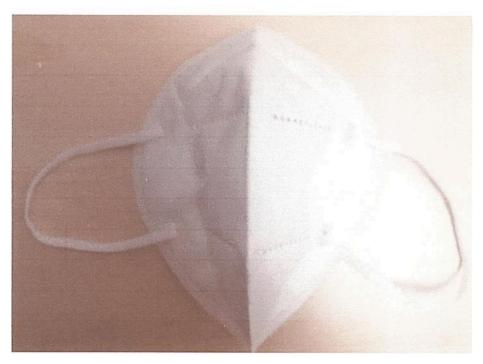
2. PPE INFORMATION:

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 F260 (7)

5. PPE DIMENSIONS:

FIT F260 (7) model has been found to be produced using standard sizes.

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6. PPE PRODUCT MATERIAL INFORMATION:

The mask is made of cotton elastic strap, non-woven fabric on the outer and inner layers and filter 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.
- Respiratory protective dimensions are evaluated according to EN 149:2001+A1:2009.
- Conditioning EN 149:2001+A1:2009 part 8.3, Penetration EN 149:2001+A1:2009 part 8.11 (EN 13274-7), Application performance EN 149:2001+A1:2009 part 8.4, Inward leakage EN 149:2001+A1:2009 part 8.5, Flammability EN 149:2001+A1:2009 part 8.6, The carbon dioxide content of the inhaled air EN 149:2001+A1:2009 part 8.7, Inhalation resistance EN 149:2001+A1:2009 part 8.9 has been tested and evaluated.

8. ANALYSIS AND EVALUATIONS:

EN 149:2001+A1:2009

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Visual inspection	Shall also the markin supplied by the manu	ng and the information			Appropriate	-	PASS
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 recieved)	1.1	0.5	2.0	2.2	2.3	1.6				
Subject 2 (As recieved)	1.3	0.5	0.2	2.4	2.2	1.3				
Subject 3 (As recieved)	1.4	0.4	2.0	1.6	2.0	1.5				
Subject 4 (As recieved)	1.1	0.3	0.2	0.5	2.2	0.9				
Subject 5 (As recieved)	0.8	0.5	2.6	3.2	2.2	1.9				
Subject 6 (After temperature conditioning)	0.7	1.4	1.2	0.7	2.2	1.2				
Subject 7 (After temperature conditioning)	0.5	1.7	1.1	2.0	0.6	1.2				
Subject 8 (After temperature conditioning)	0.8	1.1	0.8	2.2	2.1	1.4				
Subject 9 (After temperature conditioning)	0.8	1.0	0.7	2.0	0.6	1.0				
Subject 10 (After temperature conditioning)	0.9	2.0	2.2	2.0	0.8	1.6				

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TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Flammibility	Mask shall not burn burn for more than 5			Flame not seen	-	PASS	
Carbondioxide content of the inhalation air	Shall not exceed an av	verage of % 1		0,61 0,53 0,60	-	PASS	
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	/min % 20 % 6 % 1			See the table below	FFP3	PASS

Penetration of filter material	Sodium Chloride (%)	Paraffin Oil (%)	
As recieved	0.2	0.1	
As recieved	0.2	0.1	
As recieved	0.1	0.1	
After the simulated wearing treatment	0.2	0.1	
After the simulated wearing treatment	0.1	0.2	
After the simulated wearing treatment	0.1	0.2	
Mechanical strength and temperature conditioning	0.1	0.1	
Mechanical strength and temperature conditioning	0.2	0.2	
Mechanical strength and temperature conditioning	0.1	0.2	

TESTS	PARAMETER PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION	
		FFP1	FFP2	FFP3			
Compatibility with skin	Materials shall not be cause irritation or an to health			and and	Appropriate	-	PASS
Head harness	It can be donned and	emoved easily			Appropriate	•	PASS
Exhalation valve(s)	It shall withstand axia N apply for 10 s.	lly a ten	sile forc	e of 10	Appropriate	-	PASS
	If fitted, shall continuafter a continuous e L/min over a period of	xhalatio		요약하다 하기 하면 하네 뭐 !!			
Breathing Resistance	Inhalation 30L/min	0,6 mbar	0,7 mbar	1 mbar	See the table below	FFP3	PASS
	Inhalation 95L/min	2,1 mbar	2,4 mbar	3 mbar	See the table below	FFP3	PASS
	Exhalation 160L/min 3 3 3 mbar mbar mbar				See the table below	FFP3	PASS



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Breathing Resistance	Inhalation 30L/min	Inhalation 95L/min	
As recieved	0.5	1.6	
As recieved	0.5	1.5	
As recieved	0.4	1.6	
After temperature conditioning	0.5	1.5	
After temperature conditioning	0.4	1.5	
After temperature conditioning	0.4	1.5	
After the simulated wearing treatment	0.5	1.5	
After the simulated wearing treatment	0.4	1.6	
After the simulated wearing treatment	0.4	1.6	

Breathing Resistance 160L/min	Facing directly ahead	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side
As recieved	2,3	2,3	2,3	2,2	2,3
As recieved	2,2	2,3	2,3	2,2	2,2
As recieved	2,2	2,2	2,3	2,3	2,3
After temperature conditioning	2,3	2,3	2,3	2,2	2,3
After temperature conditioning	2,3	2,2	2,3	2,3	2,2
After temperature conditioning	2,2	2,2	2,2	2,3	2,3
After the simulated wearing treatment	2,2	2,3	2,3	2,3	2,3
After the simulated wearing treatment	2,3	2,3	2,3	2,3	2,2
After the simulated wearing treatment	2,2	2,3	2,3	2,3	2,2

9. DECISION PROPOSAL

Analysis and examinations FIT F260 (7) 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.

CONTROLLER : VOLKAN AKIN

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DATE : 16.11.2020