

TECHNICAL EVALUATION REPORT

Report No

: M-2020-00445

Report Date

: 16.11.2020

1. COMPANY INFORMATION:

Fit Pharm Technologies GmbH

Benzstraße 13 48619 Heek Nordrhein-Westfalen Deutschland

Tel: +491605319004

E-mail: s.babitzki@farm-innovation-team.de

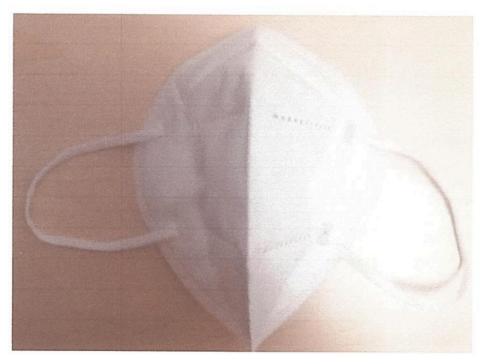
2. PPE INFORMATION:

Disposable and non-sterile half mask made of particulate protection filter material.

3. PPE TYPE IDENTIFICATION

EN 149 +A1 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking

4. PPE PICTURES



FIT F261 (9)

5. PPE DIMENSIONS:

FIT F261 (9) model has been found to be produced using standard sizes.



TECHNICAL EVALUATION REPORT

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 + A1 for ergonomics.
- Protection levels and degrees are defined by the manufacturer.
- Suitable construction materials were determined by visual inspection according to EN 149 + A1.
- Respiratory protective dimensions are evaluated according to EN 149 + A1.
- Conditioning EN 149 + A1 part 8.3, Penetration EN 149 + A1 part 8.11 (EN 13274-7), Application performance EN 149 + A1 part 8.4, Inward leakage EN 149 + A1 part 8.5, Flammability EN 149 + A1 part 8.6, The carbon dioxide content of the inhaled air EN 149 + A1 part 8.7, Inhalation resistance EN 149 + A1 part 8.9, Exhalation resistance EN 149 + A1 part 8.9 has been tested and evaluated.

8. ANALYSIS AND EVALUATIONS:

EN 149 +A1

TESTS	PARAMETER PERFOR LEVELS			Œ	RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Visual inspection	Shall also the markin supplied by the manu			Appropriate	-	PASS	
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 recieved)	5.1	4.5	6.0	6.2	6.3	5.6				
Subject 2 (As recieved)	5.3	4.5	8.1	6.4	6.2	6.1				
Subject 3 (As recieved)	5.4	4.4	6.0	5.6	6.0	5.5				
Subject 4 (As recieved)	5.1	7.6	8.4	8.3	6.2	7.1				
Subject 5 (As recieved)	4.8	7.6	6.6	7.2	6.2	6.5				
Subject 6 (After temperature conditioning)	4.7	5.4	5.2	4.7	6.2	5.2				
Subject 7 (After temperature conditioning)	4.5	5.7	5.1	6.0	4.6	5.2				
Subject 8 (After temperature conditioning)	4.8	5.1	4.8	6.2	6.1	5.4				
Subject 9 (After temperature conditioning)	4.8	5.0	4.7	6.0	4.6	5.0				
Subject 10 (After temperature conditioning)	4.9	6.0	6.2	6.0	4.8	5.6				



TECHNICAL EVALUATION REPORT

TESTS	PARAMETER PERFORMANCE LEVELS				RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Flammibility	Mask shall not burn burn for more than 5	or not to continue to		Flame not seen	-	PASS	
Carbondioxide content of the inhalation air	Shall not exceed an av	verage of % 1			0,57 0,55 0,56	-	PASS
Penetration of filter material	Sodium chloride, 95 L/min %, max	% 20	% 6	%1	See the table below	FFP2	PASS
	Paraffin oil, 95 L/min				See the table below	FFP2	PASS

Penetration of filter material	Sodium Chloride (%)	Paraffin Oil (%)	
As recieved	1.4	1.1	
As recieved	1.3	1.0	
As recieved	1.5	1.1	
After the simulated wearing treatment	1.4	1.4	
After the simulated wearing treatment	1.6	1.3	
After the simulated wearing treatment	1.6	1.2	
Mechanical strength and temperature conditioning	1.5	1.4	
Mechanical strength and temperature conditioning	1.4	1.3	
Mechanical strength and temperature conditioning	1.1	1.4	

TESTS	PARAMETER PERFORMANCE LEVELS				RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Compatibility with skin	A company service service	known to be likely to y other adverse effect		Appropriate	-	PASS	
Head harness	It can be donned and	d removed 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 continuate after a continuous e L/min over a period of	xhalatio					
Breathing Resistance	Inhalation 30L/min	0,6 mbar	0,7 mbar	1 mbar	See the table below	FFP2	PASS
	Inhalation 95L/min	2,1 mbar	2,4 mbar	3 mbar	See the table below	FFP2	PASS
	Exhalation 160L/min 3 3 3 mbar mbar mbar				See the table below	FFP2	PASS



TECHNICAL EVALUATION REPORT

Breathing Resistance	Inhalation 30L/min	Inhalation 95L/min	
As recieved	0.2	0,8	
As recieved	0.2	0,8	
As recieved	0.1	0,9	
After temperature conditioning	0.2	0,9	
After temperature conditioning	0.1	0,8	
After temperature conditioning	0.1	0,9	
After the simulated wearing treatment	0.2	0,9	
After the simulated wearing treatment	0.1	0,8	
After the simulated wearing treatment	0.1	0,8	

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	1,6	1,6	1,6	1,5	1,6
As recieved	1,5	1,6	1,6	1,5	1,5
As recieved	1,5	1,5	1,6	1,6	1,6
After temperature conditioning	1,6	1,6	1,6	1,5	1,6
After temperature conditioning	1,6	1,5	1,6	1,6	1,5
After temperature conditioning	1,5	1,5	1,5	1,6	1,6
After the simulated wearing treatment	1,5	1,6	1,6	1,6	1,6
After the simulated wearing treatment	1,6	1,6	1,6	1,6	1,5
After the simulated wearing treatment	1,5	1,6	1,6	1,6	1,5

9. DECISION PROPOSAL

Analysis and examinations FIT F261 (9) model coded personal protective equipment; Respiratory Protective Devices EN 149 + A1 - Filtered Half Masks for Protection Against Particles - Properties, Experiments and Marking standards are evaluated.

CONTROLLER : VOLKAN AKIN

SING :

DATE : 16.11.2020