Report No :135-21-02-R01

Report Date :14.01.2022

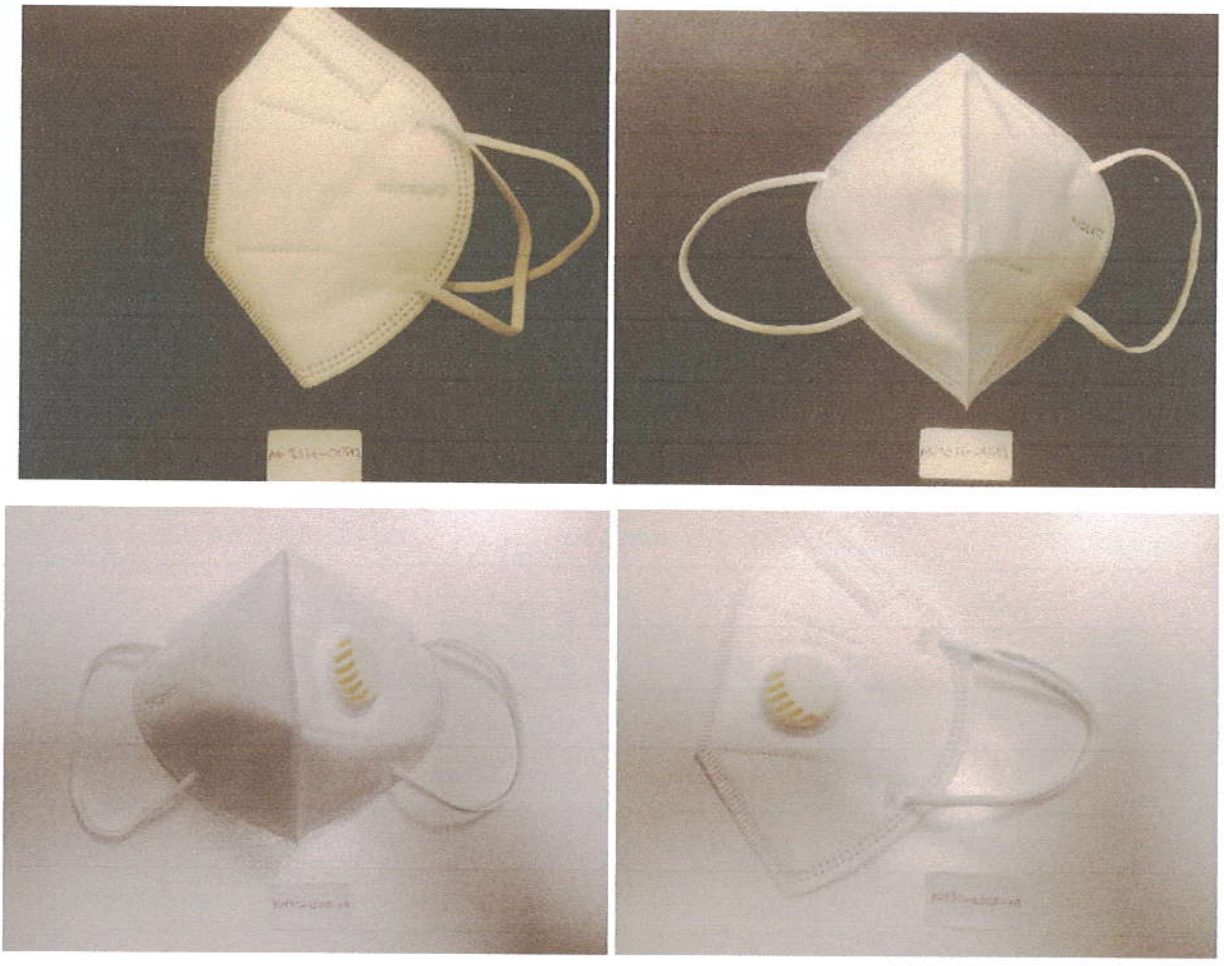
Application No :135-21-02-R01

1. **COMPANY INFORMATION:**
   GRAFOPLAS DEL NOROESTE, S.A.
   LG. A MARİSQUEİRA, S/N (POL. IND. ALMEİRAS) 15180 CULLEREDO (A CORUÑA) – ESPAÑA
   Tel: +34 981 677 677
   Fax: +34 981 677 020
   E-mail: admin@grafoplas.com

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**



MFR001G, MFVR002G

5. **PPE DIMENSIONS:**
MFR001G, MFVR002G model has been found to be produced using standard sizes.
6. **PPE PRODUCT MATERIAL INFORMATION:**
The product is made of elastic strap, exhalation valve, 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 AND EVALUATIONS:**

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

Total Inward Leakage (%) -With Valve-						
	Exercise 1	Exercise 2	Exercise 3	Exercise 4	Exercise 5	Average
Subject 1 (As received)	1,7	1,5	0,7	0,7	0,7	1,1
Subject 2 (As received)	1,7	0,5	0,3	0,4	0,5	0,7
Subject 3 (As received)	0,5	0,7	0,7	2,2	2,3	1,3
Subject 4 (As received)	0,4	0,4	0,5	0,7	0,8	0,6
Subject 5 (As received)	1,6	1,6	1,2	0,9	1,0	1,3
Subject 6 (After temperature conditioning)	1,8	3,1	3,4	2,9	3,6	3,0
Subject 7 (After temperature conditioning)	1,9	2,1	0,7	0,7	0,4	1,2
Subject 8 (After temperature conditioning)	1,0	1,6	0,4	0,4	0,7	0,8
Subject 9 (After temperature conditioning)	0,4	0,4	1,6	2,2	1,8	1,3
Subject 10 (After temperature conditioning)	0,8	0,2	0,1	0,1	0,4	0,3

Subject facial dimensions

Subject	Face Length (mm)	Face Width (mm)	Face Depth (mm)	Mouth Width (mm)
1	133	132	132	65
2	125	144	116	67
3	126	135	124	75

4	123	133	134	74
5	117	135	122	73
6	122	142	133	66
7	113	132	114	75
8	135	123	123	65
9	122	135	133	74
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	0,1	0,1
As received	0,2	0,1
As received	0,1	0,2
After the simulated wearing treatment	0,2	0,2
After the simulated wearing treatment	0,2	0,1
After the simulated wearing treatment	0,1	0,2
Mechanical strength and temperature conditioning	0,2	0,3
Mechanical strength and temperature conditioning	0,2	0,2
Mechanical strength and temperature conditioning	0,1	0,2

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

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	Shall not exceed an average of % 1				0,70 0,69	-	PASS

Carbondioxide content of the inhalation air		0,74 -With Valve- 0,77 0,71 0,72		
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.	Appropriate	-	PASS

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	0,5	1,8
As received	0,5	1,7
As received	0,4	1,7
After temperature conditioning	0,4	1,8
After temperature conditioning	0,5	1,7
After temperature conditioning	0,4	1,7
After the simulated wearing treatment	0,4	1,7
After the simulated wearing treatment	0,4	1,8
After the simulated wearing treatment	0,5	1,7
After flow conditioning	-	-
After flow conditioning	-	-
After flow conditioning	-	-

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	2,5	2,6	2,5	2,6	2,6
As received	2,6	2,6	2,5	2,6	2,6
As received	2,5	2,5	2,5	2,5	2,6
After temperature conditioning	2,6	2,6	2,6	2,6	2,5
After temperature conditioning	2,6	2,5	2,6	2,5	2,6
After temperature conditioning	2,6	2,6	2,5	2,6	2,6
After the simulated wearing treatment	2,5	2,5	2,6	2,6	2,5
After the simulated wearing treatment	2,6	2,5	2,5	2,6	2,6

After the simulated wearing treatment	2,6	2,6	2,6	2,6	2,5
After flow conditioning	-	-	-	-	-
After flow conditioning	-	-	-	-	-
After flow conditioning	-	-	-	-	-

Breathing Resistance (mbar) -With Valve-	Inhalation 30L/min	Inhalation 95L/min
As received	0,5	2,0
As received	0,5	1,9
As received	0,6	2,0
After temperature conditioning	0,5	1,9
After temperature conditioning	0,6	2,0
After temperature conditioning	0,5	2,0
After the simulated wearing treatment	0,5	1,9
After the simulated wearing treatment	0,6	1,9
After the simulated wearing treatment	0,6	2,0
After flow conditioning	0,6	2,0
After flow conditioning	0,5	2,0
After flow conditioning	0,5	1,9

Breathing Resistance 160L/min (mbar) -With Valve-	Facing directly ahead	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side
As received	2,5	2,5	2,6	2,6	2,5
As received	2,6	2,5	2,5	2,5	2,6
As received	2,5	2,6	2,5	2,5	2,5
After temperature conditioning	2,5	2,5	2,5	2,6	2,6
After temperature conditioning	2,6	2,6	2,6	2,5	2,5
After temperature conditioning	2,6	2,5	2,5	2,5	2,6
After the simulated wearing treatment	2,6	2,6	2,6	2,6	2,6
After the simulated wearing treatment	2,5	2,5	2,5	2,5	2,6
After the simulated wearing treatment	2,6	2,6	2,5	2,6	2,5
After flow conditioning	2,5	2,6	2,5	2,5	2,5
After flow conditioning	2,5	2,5	2,5	2,6	2,6
After flow conditioning	2,6	2,6	2,6	2,5	2,5

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

9. DECISION PROPOSAL

Analysis and examinations MFR001G, MFVR002G 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. It is recommended to be certified at the performance levels specified as a result of technical evaluations.

10. ATTACHMENTS

- Basic Health Safety Requirements
- Risk Assessment
- Test Reports (M-2021-01701, M-2021-01512)
- User Instruction

Reason for Revision : Model with valve has been added.

CONTROLLER **: VOLKAN AKIN**

SINGNATURE **:**

DATE **: 14.01.2022**