

EU Type-Examination Certificate

Certificate No : 115-21-09-01-R02
Certification Date / Certificate Validity Date : 25.01.2022-19.08.2022
Document Validity Period : 1 Year
Company Name and Address : CARINE EUROPE GmbH
Ammannstraße 12, 86167 Augsburg, Germany
Product Name / Models : CM-FM002
Directive : 2016/425 REGULATION
Module / Category : MODULE C2 / CATEGORY III
Technical Evaluation Report No : MNA Certificate no: 115-21-09-01-R02
Product Type:
- EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles

Product Material Information: CM-FM002 model products are manufactured using fabric, elastic strap, nose clip, filter layer.

Reason for Revision : Erratum has been corrected.

Erhan ÜSTÜNEL
25.01.2022
Approver



Okan AKEL
25.01.2022
General manager



Notified Body Number: 2841

Report No : 115-21-09-01-R02

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Application No : 115-21-09-01-R02

1. COMPANY INFORMATION:

CARINE EUROPE GmbH
Ammannstraße 12, 86167 Augsburg, Germany

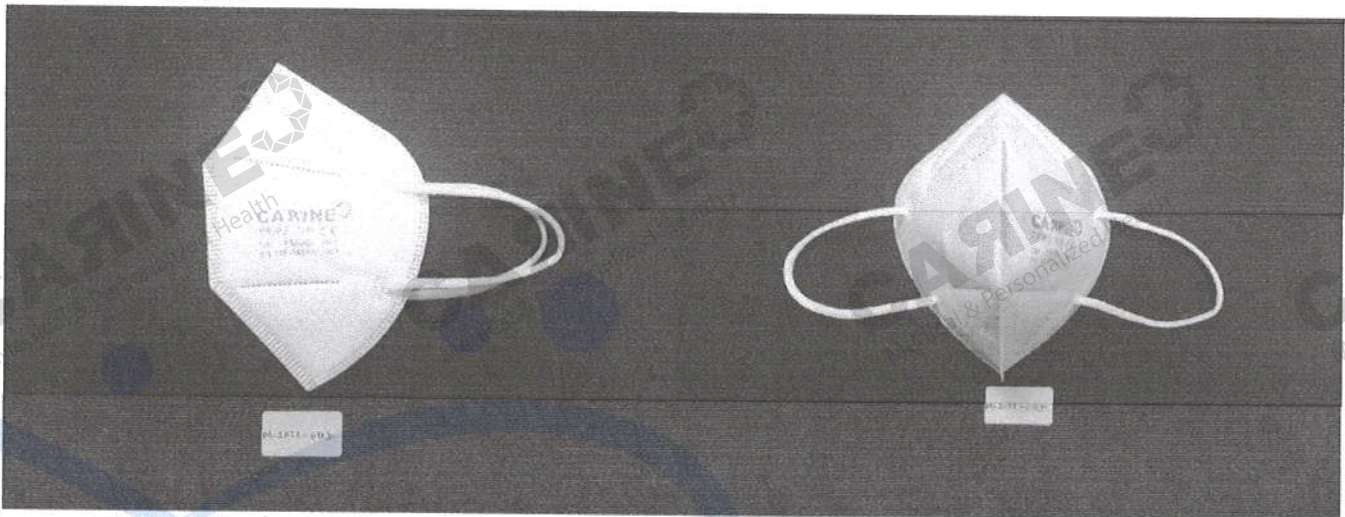
2. PPE INFORMATION:

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



CM-FM002

5. PPE DIMENSIONS:

CM-FM002 model has been found to be produced using standard and small sizes.

6. PPE PRODUCT MATERIAL INFORMATION:

The mask is made of elastic strap, nonwoven 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.

8. ANALYSIS AND EVALUATIONS:

EN 149:2001 +A1:2009

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			

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PRODUCTION CONTROL PLUS SUPERVISED PRODUCT
CHECK AT RANDOM INTERVALS
(MODULE C2, ANNEX VII) (115-21-09-01-R02)**

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

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Subject 9 (After temperature conditioning)	7,1	6,5	6,4	6,4	6,3	7,1
Subject 10 (After temperature conditioning)	4,1	6,3	6,1	4,1	4,4	4,1

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	FFP2	PASS
	Paraffin oil, 95 L/min % , max	% 20	% 6	% 1	See the table below	FFP2	PASS
Penetration of filter material					Sodium Chloride (%)	Paraffin Oil (%)	
As recieved					2,2	2,6	
As recieved					2,2	2,9	
As recieved					2,4	2,5	
After the simulated wearing treatment					2,5	2,5	
After the simulated wearing treatment					2,3	2,9	
After the simulated wearing treatment					2,3	3,1	
Mechanical strength and temperature conditioning					3,6	3,9	
Mechanical strength and temperature conditioning					3,5	4,1	
Mechanical strength and temperature conditioning					3,7	3,9	

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				0,74	-	PASS

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Carbondioxide content of the inhalation air		0,71 0,73		
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.	-	-	-

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	FFP2	PASS
	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 recieved	0,3	1,3
As recieved	0,3	1,4
As recieved	0,3	1,4
After temperature conditioning	0,3	1,3
After temperature conditioning	0,4	1,3
After temperature conditioning	0,4	1,3
After the simulated wearing treatment	0,4	1,3
After the simulated wearing treatment	0,4	1,4
After the simulated wearing treatment	0,4	1,4
After the flow conditioning	-	-
After the flow conditioning	-	-
After the 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 recieved	2,2	2,1	2,2	2,2	2,2
As recieved	2,1	2,2	2,1	2,2	2,1
As recieved	2,1	2,2	2,1	2,2	2,1
After temperature conditioning	2,2	2,1	2,0	2,2	2,2
After temperature conditioning	2,2	2,1	2,1	2,2	2,2
After temperature conditioning	2,2	2,2	2,2	2,2	2,2
After the simulated wearing treatment	2,2	2,2	2,2	2,1	2,2
After the simulated wearing treatment	2,2	2,2	2,2	2,1	2,2

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After the simulated wearing treatment	2,2	2,2	2,2	2,1	2,2
After the flow conditioning	-	-	-	-	-
After the flow conditioning	-	-	-	-	-
After the flow conditioning	-	-	-	-	-

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

Analysis and examinations CM-FM002 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-2021-01830)
- User Instruction

Reason for Revision : Erratum has been corrected.

CONTROLLER : Erhan ÜSTÜNEL

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DATE : 25.01.2022

