Notified Body Number: 2841

EU Type-Examination Certificate

Certificate No	: 115-21-09-R01
Certification Date / Certificate Validity Date	: 26.08.2021-09.08.2026
Document Validity Period	: *5 Years*
Company Name and Address	: CARINE EUROPE GmbH Ammannstraße 12, 86167 Augsburg, Germany
Product Name / Models	: CM-FM002
Directive	: 2016/425 REGULATION
Module / Category	: *MODULE B / CATEGORY III*
Technical Evaluation Report No	: 115-21-09-R01

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: *Different size product has been added.*

Volkan AKIN	***Okan AKEL***
26.08.2021	***26.08.2021***
Approver	***General manager***

MNA Laboratuvarları San. Tic.Ltd .Şti
Adres: Küçükbakkalköy Mahallesi Yenidoğan Cad.No:21 Ataşehir/ İstanbul
Tel: 0216 574 07 08 Faks: 0216 575 13 31 www.mnalab.com

Notified Body Number: 2841

ATTACHMENTS (115-21-09-R01)

To certify the PPE product at Category III level, C2 or D module is accompanied by applying one of the conformity assessment methods along with the EU Type Examination (Module B).

Model : CM-FM002

PPE SPECIFICATION	PERFORMANCE LEVELS
Classification	FFP2
Reusable / Single Shift Use	NR

PPE produced as a single unit to fit an individual user, all the necessary instructions for manufacturing such PPE on the basis of the approved basic model:

MARKING

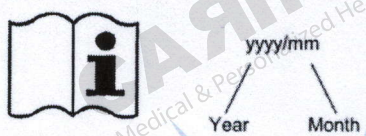
MANUFACTURER:
SITE I: CARINE EUROPE GMBH
RÖNTGENSTR. 40 86368 GERSTHOFEN GERMANY
SITE II: AYDAĞ TEDAVİ ve SAĞLIK HİZ. SAN. TİC. A.Ş.
YENIBOSNA MERKEZ MH. CEMAL ULUSOY CD. NO:57/2 34197
BAHÇELIEVLER/İSTANBUL TURKEY
PPE TYPE:

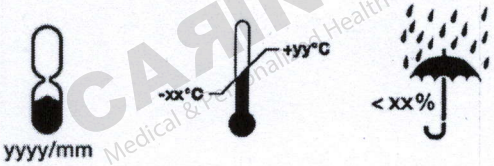
- EN 149:2001+ A1:2009 Respiratory protective devices - Filtering half masks to protect against particles

MODEL: CM-FM002
PRODUCT SIZE: Standard and small
PICTOGRAM AND PERFORMANCE LEVELS:

EN 149:2001+ A1:2009 FFP2 NR

CE





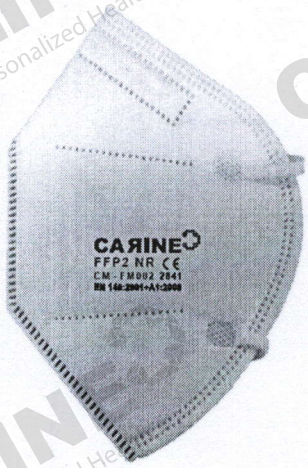
NB 2841

Or Condition of Storage

Notified Body Number: 2841

ATTACHMENTS (115-21-09-R01)

MNA LABORATORIES SAN. TIC. LTD. ŞTİ declares that the above-mentioned product meets the requirements of the directive according to the EU Directive 2016/425, the safety of the product is covered by the conditions and use specified in this certificate and in the technical file.

PRODUCT PICTURES
 SMALL SIZE  STANDART SIZE CM-FM002

DOCUMENTS IN THE TECHNICAL FILE
- Basic Health Safety Requirements - Risk Assessment - Test Reports - Technical Report

MNA LABORATUVARLARI SAN. TİC. LTD. ŞTİ.	MNA LABORATUVARLARI
	TECHNICAL EVALUATION REPORT (115-21-09-R01)

Report No : 115-21-09-R01

Report Date : 26.08.2021

Application No : 115-21-09-R01

1. **COMPANY INFORMATION:**

CARINE EUROPE GmbH
Ammannstraße 12, 86167 Augsburg, Germany
Production Facility-1: Röntgenstraße 40 / 86368 Gersthofen / Germany
Production Facility-2: Aydağ Tedavi Ve Sağlık Hiz. San. Tic. A.Ş.
Yenibosna Merkez Mh. Cemal Ulusoy Cd. No:57/2 34197 Bahçelievler/İstanbul Turkey
Tel: +49 821 45560525
Fax: +49 821 45560524
Mail: info@carine-medical.com

2. **PPE INFORMATION:**

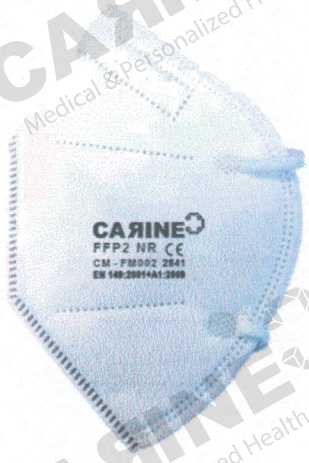
Disposable and non-sterile half mask made of particulate protection fitler material.

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**

SMALL SIZE



STANDART SIZE

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 product 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 AND EVALUATIONS:

EN 149:2001 +A1:2009

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Banned Azo Dyes	< 30 mg/kg				Not applicable	-	Not applicable
Part 7.3 Visual inspection	Shall also the marking and the information supplied by the manufacturer				Appropriate	-	PASS
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 recieved)	7,0	6,0	6,0	7,2	5,5	6,3
Subject 2 (As recieved)	6,7	6,0	7,2	5,5	5,4	6,2
Subject 3 (As recieved)	6,4	6,5	4,9	7,2	7,6	6,5
Subject 4 (As recieved)	7,8	7,2	6,9	7,3	7,6	7,4
Subject 5 (As recieved)	6,1	7,3	6,7	4,4	6,2	6,1

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

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	4,4	4,4
As recieved	4,6	4,4
As recieved	4,4	4,8
After the simulated wearing treatment	4,3	5,0
After the simulated wearing treatment	4,7	4,7
After the simulated wearing treatment	4,6	5,1
Mechanical strength and temperature conditioning(120mg)	5,6	5,7
Mechanical strength and temperature conditioning(120mg)	5,8	5,9
Mechanical strength and temperature conditioning(120mg)	5,6	5,8

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	0,66 0,77 0,75	-	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	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	0,5	1,7
As recieved	0,4	1,6
As recieved	0,4	1,6
After temperature conditioning	0,4	1,6
After temperature conditioning	0,5	1,6
After temperature conditioning	0,4	1,7
After the simulated wearing treatment	0,5	1,6
After the simulated wearing treatment	0,5	1,6
After the simulated wearing treatment	0,5	1,7
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	2,7	2,8	2,7	2,8	2,7
As recieved	2,8	2,8	2,7	2,7	2,8
As recieved	2,8	2,8	2,7	2,7	2,7

After temperature conditioning	2,8	2,7	2,8	2,7	2,8
After temperature conditioning	2,8	2,7	2,8	2,7	2,7
After temperature conditioning	2,8	2,7	2,8	2,7	2,7
After the simulated wearing treatment	2,8	2,7	2,8	2,7	2,8
After the simulated wearing treatment	2,8	2,7	2,8	2,7	2,8
After the simulated wearing treatment	2,7	2,8	2,7	2,8	2,7
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 PROPOSAL

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. 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
- User Instruction
- Test report (M-2021-01279)

Reason for revision : Different size product has been added.

CONTROLLER : VOLKAN AKIN

SIGNATURE :

DATE : 26.08.2021