

Certificate of Compliance



No. 4M20031

Technical Construction File no. 20ZCTS0310010LR

Certificate's
Holder:

For more information, visit www.3M.com/Products/Coatings

Certification ECM
Mark:



Product:
Model(s):

Disposable face mask
MK-KZ001

Verification to:

Standard:
EN 149:2001+A1:2009

related to CE Directive(s):
R 2016/425 (Personal Protective Equipment)

Remark: The product(s) has been verified on a voluntary basis. The product(s) satisfies the requirements of the Certification Mark of ECM, in reference to the above listed Standard(s). The above Compliance Mark can be affixed on the product(s) accordingly to the ECM regulation about its release and its use. The regulation can be found at www.entecerma.it. This Certificate of Compliance can be checked for validity at www.entecerma.it

This verification doesn't imply assessment of the production of the product(s).

Additional information, clarification about the CE Marking:



We attest that a TCF for the **CE** Marking process is in place. Whereas the Manufacturer is Responsible to start the **CE Marking Certification Procedure** through an appointed Notified Body and the perform all the necessary activities, as required by the Directive and accepted by the Notified Body, before placing the **CE** Mark on the product(s).

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Expiry date 11 March 2025

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Clause	Requirement – Test	Result - Remark	Verdict
5	Classification		--
	Particle filtering half masks are classified according to their filtering efficiency and their maximum total inward leakage. There are three classes of devices:		P
	- FFP1		N
	- FFP2	>95%	P
	- FFP3		N
6	Designation		--
	Particle filtering half masks meeting the requirements of this European Standard. Year of publication, classification, option	Particle filtering half mask EN 149:2001+A1:2009 FFP2 NR.	P
7	Requirements		--
7.1	General		P
	All test all test samples shall meet the requirements.	Complied the requirement, see below	P
7.2	Nominal values and tolerances		P
	Unless otherwise specified, the values stated in this European Standard are exeperature limits.		P
7.3	Visual inspection		P
	The visual inspection shall also include the marking and the information supplied by the manufacturer.	Clear marking is provided, see sample body	P
7.4	Packaging		P
	Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.		P
7.5	Material		P
	Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used. Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	Comfortable wearing, when releasing no hazards is produced.	P
7.6	Cleaning and disinfecting		N
	If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer.	It's is not re-usable.	N
7.7	Practical performance		P
	The particle filtering half mask shall undergo practical performance tests under realistic conditions.	Complied, see append test.	P
7.8	Finish of parts		P
	come into contact with the wearer shall have no sharp edges or burrs		P
7.9	Leakage	See append table 8.5	P
7.9.1	Total inward leakage		P
	The laboratory tests shall wearer to protect with high probability against the potential hazard to be expected.	Enough safe condition is Provide.	P



EN 149			
Clause	Requirement – Test	Result - Remark	Verdict
	Exercise results for total inward leakage shall be not greater than		P
	25 % for FFP1 11% for FFP2 5% for FFP3	FFP2, Not exceed 11%	P
	And, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than.		P
	22 % for FFP1 8 % for FFP2 2 % for FFP3.	FFP2, Not exceed 8%	P
7.9.2	Penetration of filter material		P
	The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.	see append table 7.92	P
7.10	Compatibility with skin		P
	Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.		P
7.11	Flammability		P
	The material used shall not present a danger for the wearer and shall not be of highly flammable nature.		P
7.12	Carbon dioxide content of the inhalation air		P
	The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0% (by volume).	<1.0%	P
7.13	Head harness		P
	Head harness shall be designed can be donned and removed easily and adjustable or selfadjusting and sufficiently robust to hold the particle.	Head harness is donned and removed easily	P
7.14	Field of vision		P
	Field of vision is acceptable in practical performance tests.	Clear field of vision when wearing	P
7.15	Exhalation valve(s)		P
	A particle filtering half mask may have one or more exhalation valve(s) and shall function correctly in all orientations.	One valve provided	P
	Exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device.	Clearly function	P
	Exhalation valve(s) shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.		P
	Exhalation valve housing is attached to the faceblank, and withstand axially a tensile force of 10 N applied for 10 s.		P
7.16	Breathing resistance		P
	Breathing resistances apply to valved and valveless and shall meet the requirements.		P
7.17	Clogging		N
	General		N
	For single-use devices clogging test is an optional test.		N
	Devices designed to be resistant to clogging, shown by a slow increase		N



EN 149			
Clause	Requirement – Test	Result - Remark	Verdict
9.1.2	Type-identifying marking.		P
9.1.3	Classification: FFP1, FFP2, FFP3.	FFP2 NR	P
9.1.4	The number and year of publication of this European Standard.		P
9.1.5	At least the year of end of shelf life.		P
9.1.6	The sentence 'see information supplied by the manufacturer', at least in the official language(s) of the country of destination, or by using the pictogram as shown in Figure 12b.		P
9.1.7	The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram, as shown in Figures 12c and 12d.	See product manual	P
9.1.8	The packaging of those particle filtering half masks passing the dolomite clogging test shall be additionally marked with the letter "D".		N
9.2	Particle filtering half mask		P
	Particle filtering half masks complying with this European Standard shall be clearly and durably marked with the following:		P
9.2.1	The name, trademark or other means of identification of the manufacturer or supplier.		P
9.2.2	Type-identifying marking.		P
9.2.3	The number and year of publication of this European Standard.		P
9.2.4	The symbols FFP1, FFP2 or FFP3 according to class.	FFP2 NR	P
9.2.5	If appropriate the letter D (dolomite) in accordance with clogging performance. This letter shall follow the class designation (see 9.2.4).		N
9.2.6	Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.		N



Clause	Requirement – Test	Result - Remark	Verdict
	The specified breathing resistances shall not be exceeded before the required dust load of 833 mg·h/m ³ .		N
7.17.2	Breathing resistance		N
7.17.2.1	Valved particle filtering half masks		N
7.17.2.2	Valveless particle filtering half masks		N
7.17.3	Penetration of filter materia		N
	All types claimed to meet the clogging requirement shall also meet the penetration requirements given in 7.9.2 after the treatment.		N
7.18	Demountable parts		N
	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.	No such demountable part	N

8	Testing		--
8.1	General		P
	No special measuring devices and methods are specified, commonly used devices and methods shall be used.		P
8.2	Visual inspection		P
	The visual inspection is carried out appropriate by the test house prior to laboratory or practical performance tests.		P
8.3	Conditioning		P
8.3.1	Simulated wearing treatment		P
	A breathing machine is adjusted to 25 cycles/min and 2,0 l/stroke.	25 cycles/min 2,0 l/stroke.	P
	For testing, a saturator is incorporated in the exhalation line between the breathing machine and the dummy head,	A saturator incorporated by breathing machine and the dummy head.	P
	The spilling out of the dummy's mouth and contaminating the particle filtering half mask the head shall be incline	Incline considered	P
8.3.2	Temperature conditioning		P
	Exposet masks to the following thermal cycle:		P
	a) for 24 h to a dry atmosphere of (70 ± 3) °C;		P
	b) for 24 h to a temperature of (-30 ± 3) °C;		P
	Allow to return to room temperature for at least 4 h between exposures and prior to subsequent testing.	4 h to paid for	P
8.3.4	Flow conditioning		P
	A total of 3 valved particle filtering half masks shall be tested, one as received and two temperature conditioned in accordance with 8.3.2.		P

9	Marking		--
9.1	Packaging		P
	The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.	Complied, clearly marked	P
9.1.1	The name, trademark or other means of identification of the manufacturer or supplier.		P



Attachments: Test table

Table 7.9.2		Penetration of test aerosol test					P
Item	Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
Sodium chloride test 95 l/min		5.6	5.7	5.5	5.6	5.7	5.6
Paraffin oil test 95 l/min		5.4	5.6	5.7	5.7	5.6	5.5

Table 8.5		Leakage test				P
Item	Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
NaCl flow rate (L/min)		90	100	120	110	120
NaCl aerosol (um)		0.3	0.3	0.3	0.3	0.3
0.3Pumping flow rate (L/min)		30	30	30	30	30
NaCl concentration before mask (Mg/m3)		2	2	2	2	2
NaCl concentration after mask (Mg/m3)		0.05	0.06	0.07	0.08	0.06
Note: Test ark volume is 2m ³ Average Leakage ratio is 8%<11% Calculation formula as below : $P(\%) = \frac{C_2}{C_1} \times \left(\frac{t_{IN} + t_{EX}}{t_{IN}} \right) \times 100$						

Table 8.9.2		Exhalation resistance test				P
Item	Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Inhalation gas velocity (L/min)		160	160	160	160	160
Maximum resistance (mbar)		2.45	2.47	2.45	2.46	2.46
Conclusion: Maximum permitted resistance < 3.0 mbar						

Table 8.9.3		Inhalation resistance test				P
Item	Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Inhalation gas velocity (L/min)		30	30	30	30	30
Maximum resistance (mbar)		0.42	0.44	0.44	0.45	0.43
Conclusion: Maximum Inhalation resistance < 0.7 mbar						



Table 8.9.3.2		Inhalation resistance test				P
Item	Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Inhalation (L/min)		95	95	95	95	95
Maximum resistance (mbar)		2.12	2.14	216	2.15	2.14
Conclusion: Maximum Inhalation resistance < 2.4mbar						



Details of: Disposable face mask, model : MK-KZ001

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View:

☒ [X] general

☐ [] front

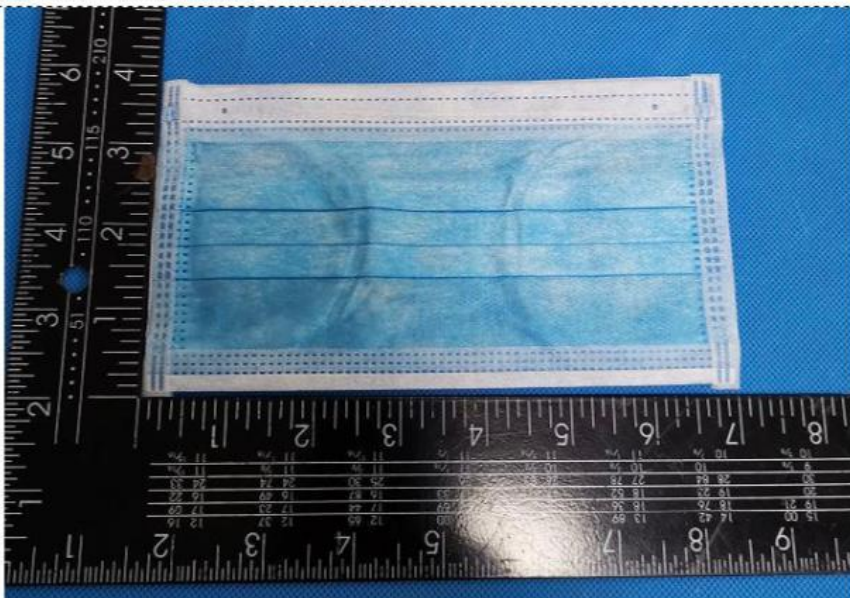
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Details of: Disposable face mask, model : MK-KZ001

View:

☐ [] general

☒ [X] front

☐ [] rear

☐ [] right

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- End of Test Report -



