



2020

CERTIFICATE OF REGISTRATION

This certifies that:

is registered with the U.S. Food and Drug Administration for FY 2019 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Registration:

3012309743

DUNS No.:

56-045-1976

Device Classification Name:

Respirator,surgical (Face Mask)

Product Code:

MSH

Device Listing Number:

D374616

U.S. Agent:

Registrar Corp

144 Research Drive, Hampton, Virginia, 23666, USA

Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. Registrar Corp assumes no liability to any person or entity in connection with the foregoing.

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Russell K. Statman
Russell K. Statman

Executive Director

Registrar Corp

Dated: *May 6, 2019*

Certificate of Compliance



No. 0B200326E.YOP00099

Certificate's
Holder:

Certification ECM
Mark:



Product: Disposable mask (Not sterile)
Model(s): OP1510 (FFP2 NR D)

Verification to: Standard:
EN 149:2001+A1:2009

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

Remark: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products accordingly to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:



The manufacturer is responsible for the CE Marking process. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

Issuance date: 26 March 2020

Expiry date: 25 March 2025

Reviewer
Technical expert
Amanda Payne

Approver
ECM Service Director
Luca Bedonni

Ente Certificazione Macchine Srl

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TEST REPORT

Customer:

Address:

Report Number: ACIC20200325137RKY

Total Page: 8 Pages

Report on the submitted sample said to be:

Sample name: Disposable mask

Trademark: N/A

Model: OP17595

Classification: FFP2

Manufacturer:

Address:

Sample received date: Mar. 13, 2020

Testing period: Mar. 13, 2020- Mar. 25, 2020

Test (Issue) laboratory: Shenzhen A Commitment Inspection&Certificate Co.,LTD.

Test location: No.164-165, Pengda Road, Longgang Street, Longgang District, Shenzhen, China

Test Conclusion:

Test Requested	Conclusion
EN 149: 2001+A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking	PASS

***** FOR FURTHER DETAILS, PLEASE REFER TO THE FOLLOWING PAGE(S) *****

Signed for and on behalf of ACIC

Tested by:

Sophie Lee

Approved by:

Jack



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Test data sheet

The following tests were carried out according to The manufacturers technical requirements and refer to EN 149: 2001+A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking

Note: P means meet the requirement, N/A means not applicable, F means does not meet the requirement.

EN 149			
Clause	Requirement-Test	Result-Remark	Verdict
5	Classification		P
	Particle filtering half masks are classified according to their filtering efficiency and their maximum total inward leakage.	FFP2 NRD	P
6	Particle filtering half masks meeting the requirements of this European Standard. Year of publication, classification	"D" clearly marked	P
7	Requirements		P
7.1	All test all test samples shall meet the requirements	Complied see bellow	P
7.2	Nominal values and tolerances		P
	Unless otherwise specified, the values stated in this European Standard are expeature limits	Actual using value is clear	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
	offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.	Distinct design and warning are made on packaging, see sample body	P
7.5	Material		P
	Materials suitable to withstand handling and wear over the period. Any material from the filter media released 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
	The materials used shall withstand the cleaning and disinfecting	Single-use equipment	N
7.7	Practical performance		P
	The particle filtering half mask shall undergo practical performance tests under realistic conditions.	Complied, see bellow test	P
7.8	Finish of parts	Soft equipment	N

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	come into contact with the wearer shall have no sharp edges or burrs		N
7.9	Leakage		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
	Exercise results for total inward leakage shall be not greater than 22 % for FFP1 8 % for FFP2 2 % for FFP3	FFP2, not exceed 8%	P
7.9.2	Penetration of filter material		P
	meet the requirements of Table 2.	Complied, see below test	P
7.10	Compatibility with skin		P
	the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.	Have no irritation or adverse effect to skin and health	P
7.11	Flammability	Have no such hazard	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		N
	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		
	Head harness shall be designed can be donned and removed easily and adjustable or self-adjusting and sufficiently robust to hold the particle	The designing is considered	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	Complied, see below	P

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	300 l/min over a period of 30 s.		
	Exhalation valve housing is attached to the faceblank, and withstand axially a tensile force of 10 N applied for 10 s.	Enough strong	P
7.16	Breathing resistance		P
	Ereathing resistances apply to valved and valveless and shall meet the requirements	Complied, see below test	P
7.17	Clogging		N
7.17.1	General	single-use device	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
	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		P
7.17.2.1	Valved particle filtering half masks		P
7.17.2.2	Valveless particle filtering half masks		P
	After clogging the inhalation and exhalation resistances shall not exceed ¾ FFP1: 3 mbar ¾ FFP2: 4 mbar ¾ FFP3: 5 mbar	¾ FFP2: , not exceed 4 mbar	P
	at 95 l/min continuous flow.		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	No any such part	N
	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.		
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.	See user manual	P
9.1.2	Type-identifying marking.		P
9.1.3	Classification: FFP1, FFP2, FFP3.	FFP2 NRD	P
9.1.4	The number and year of publication of this	See above	P

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	European Standard.		
9.1.5	At least the year of end of shelf life.	18 Months	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.	English used	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 user 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".		P
9.2	Particle filtering half mask		P
	Particle filtering half masks		P
	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.	See above	P
9.2.4	The symbols FFP1, FFP2 or FFP3 according to class.	FFP2 NRD	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
10	Information to be supplied by the manufacturer		P
10.1	Information supplied by the manufacturer shall be at least in the official language(s) of the country of destination.	English	P
10.3	The information supplied by the manufacturer shall contain all information necessary for trained and qualified persons on ¾ application/limitations; ¾ the meaning of any colour coding;	See user manual	P
	¾ checks prior to use; ¾ donning, fitting;	See user manual	P

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	$\frac{3}{4}$ use; $\frac{3}{4}$ maintenance (e.g. cleaning, disinfecting), if applicable; $\frac{3}{4}$ storage; $\frac{3}{4}$ the meaning of any symbols/pictograms used of the equipment.		
10.4	The information shall be clear and comprehensible. If helpful, illustrations, part numbers, marking shall be added.	Clearly considered	P
10.5	Warning shall be given against problems likely to be encountered, for example: $\frac{3}{4}$ fit of particle filtering half mask (check prior to use); $\frac{3}{4}$ it is unlikely that the requirements for leakage will be achieved if facial hair passes under the face seal; $\frac{3}{4}$ air quality (contaminants, oxygen deficiency); $\frac{3}{4}$ use of equipment in explosive atmosphere.	See user manual	P
10.6	The information shall provide recommendations as to when the particle filtering half mask shall be discarded.		P

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Attachments: test table

Table 8.5		Leakage test				P
Item	Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
NaCl flow rate (L/min)		90	105	105	110	120
NaCl aerosol (um)		0.3	0.3	0.3	0.3	0.3
Pumping 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)		0.17	0.16	0.16	0.17	0.16
<p>Note: Test ark volume is 2m³ Average Leakage ratio is 8.20%<11% Calculation formula as below :</p> $P(\%) = \frac{C_2}{C_1} \times \left(\frac{t_{IN} + t_{EX}}{t_{IN}} \right) \times 100$						

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Table 8.9.1 Breathing 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)		0.35	0.33	0.34	0.52	0.44
Note: Maximum permitted resistance < 0.6 mbar						

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)		95	95	95	95	95
Maximum resistance (mbar)		2.04	2.06	2.02	2.01	2.01
Note: Maximum permitted resistance < 2.1 mbar						

Table 8.9.3 Breathing resistance test						P
Item	Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Exhalation (L/min)		160	160	160	160	160
Maximum resistance (mbar)		2.55	2.55	2.57	2.54	2.53
Note: Maximum permitted resistance < 3.0 mbar						

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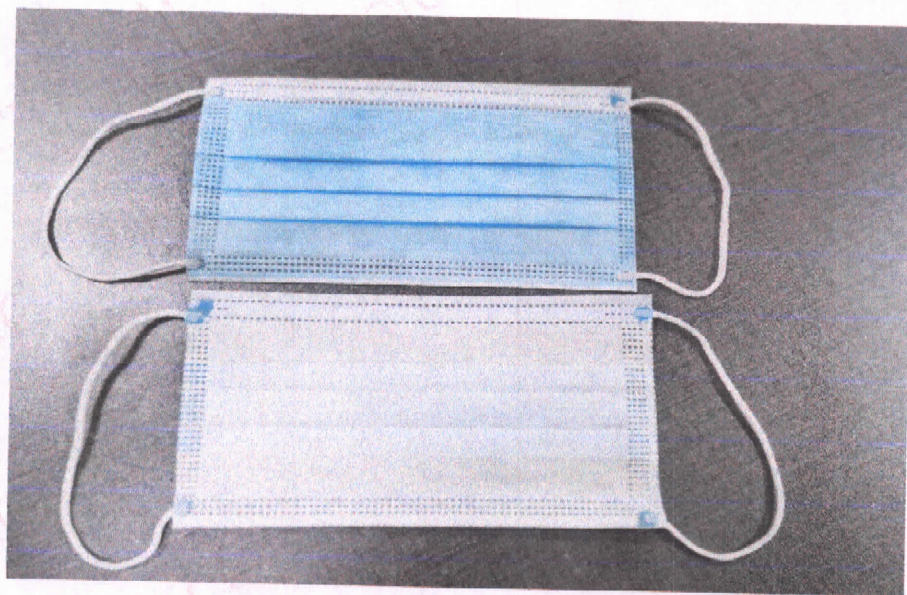
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Attachments: one of real photos test samples**Photo 1**

View:

☒ front☐ Pack☐ right side☐ left side☐ internal***** THE END OF REPORT *****

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