

No. XMT0202001021LY/PPE

Medical Device Branch of Zhangzhou Easepal Industrial Co., Ltd

# CE Technical Documents

**Product name: Personal protective mask**

**Applied Directive : Regulation on Personal Protective Equipment (R 2016/425)**

**Document No.: XMT0202001021LY/PPE**

**Revision: V0**

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<b>Test Item Description</b>		
Product Name :	Personal protective mask	
Model/Type Reference :	D13003	
Standard :	EN 149:2001+A1:2009 Respiratory protective devices — Filtering half masks to protect against particles — Requirements, testing, marking	
<b>Test Case Verdicts</b>		
Test case does not apply to the test object :	N(.A .)	
Test item does meet the requirement :	P(ass)	
Test item does not meet the requirement :	F(ail)	
<b>General Remarks</b>		
<ul style="list-style-type: none"> <li>◆ This report shall not be reproduced except in full without the written approval of the testing laboratory.</li> <li>◆ The test results presented in this report relate only to the item tested.</li> <li>◆ Clause numbers between brackets refer to clauses in EN 149:2001+A1:2009.</li> <li>◆ “(see remark #)” refers to a remark appended to the report.</li> <li>◆ “(see Annex #)” refers to an annex appended to the report.</li> <li>◆ Throughout this report a point is used as the decimal separator.</li> </ul>		

Clause	Requirement-Test	Result-Remark	Verdict
<b>EN 149:2001+A1:2009</b> <b>Respiratory protective devices — Filtering half masks to protect against particles — Requirements, testing, marking</b>			
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: FFP1, FFP2 and FFP3.	FFP2	P
	The protection provided by an FFP2 - or FFP3 - device includes that provided by the device of lower class or classes.	provided by an FFP2	P
6	Designation		-
	Particle filtering half masks meeting the requirements of this European Standard shall be designated in the following manner:		P
	Particle filtering half mask EN 149, year of publication, classification, option (where "D" is an option for a non re-useable particle filtering half mask and mandatory for re-useable particle filtering half mask)."		P
7	Requirements		-
7.1	General		-
	In all tests all test samples shall meet the requirements.		P
7.2	Nominal values and tolerances		-
	Unless otherwise specified, the values stated in this European Standard are expressed as nominal values. Except for temperature limits, values which are not stated as maxima or minima shall be subject to a tolerance of $\pm 5\%$ . Unless otherwise specified, the ambient temperature for testing shall be $(16 - 32)^\circ\text{C}$ , and the temperature limits shall be subject to an accuracy of $\pm 1^\circ\text{C}$ .	Accord	P
7.3	Visual inspection		-
	The visual inspection shall also include the marking and the information supplied by the manufacturer.		P
7.4	Packaging		-
	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		-

Clause	Requirement-Test	Result-Remark	Verdict
	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.		P
7.6	Cleaning and disinfecting		-
	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."	Non Reusable	N/A
7.7	Practical performance		-
	The particle filtering half mask shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that cannot be determined by the tests described elsewhere in this standard.	Details see Clause 8.4	P
7.8	Finish of parts		-
	Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.		P
7.9	Leakage		-
7.9.1	Total inward leakage		-
	The laboratory tests shall indicate that the particle filtering half mask can be used by the wearer to protect with high probability against the potential hazard to be expected.	Details see Clause 8.5	P
7.9.2	Penetration of filter material		-
	The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.	TEST 1:0.61 TEST 2:0.62 TEST 3:0.60	P
7.10	patibility with skin		-
	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		-
	The material used shall not present a danger for the wearer and shall not be of highly flammable nature.	Details see Clause 8.6	P
7.12	Carbon dioxide content of the inhalation air		-
	The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume).	0.5%	P
7.13	Head harness		-
	The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.		P

Clause	Requirement-Test	Result-Remark	Verdict
7.14	Field of vision		-
	The field of vision is acceptable if determined so in practical performance tests.		P
7.15	Exhalation valve(s)		-
	A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations		N/A
7.16	Breathing resistance		-
	The breathing resistances apply to valved and valveless particle filtering half masks and shall meet the requirements of Table 2.	Inhalation at 30l/min:35-40Pa Inhalation at 90l/min:140-165Pa Exhalation at 160l/min:217-252Pa	P
7.17	Clogging		-
7.17.1	General		-
	!For single shift use devices, the clogging test is an optional test. For re-usable devices the test is mandatory."		N/A
7.17.2	Breathing resistance		-
7.17.2.1	Valved particle filtering half masks		-
	After clogging the inhalation resistances shall not exceed FFP1: 4 mbar FFP2: 5 mbar FFP3: 7 mbar	FFP2: 5 mbar	-
7.17.2.2	Valveless particle filtering half masks		-
	After clogging the inhalation and exhalation resistances shall not exceed FFP1: 3 mbar FFP2: 4 mbar FFP3: 5 mbar at 95 l/min continuous flow.	FFP2: 4 mbar	-
7.17.3	Penetration of filter material All types (valved and valveless) of particle filtering half masks claimed to meet the clogging requirement shall also meet the requirements given in 7.9.2, for the Penetration test according to EN 13274-7, after the clogging treatment.		N/A
7.18	Demountable parts		-
	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.		N/A
8	Testing		-

Clause	Requirement-Test	Result-Remark	Verdict
8.1	General		-
	If no special measuring devices and methods are specified, commonly used devices and methods shall be used.		P
8.2	Visual inspection		-
	The visual inspection is carried out where appropriate by the test house prior to laboratory or practical performance tests.		P
8.3	Conditioning		-
8.3.1	Simulated wearing treatment		-
	Conditioning by simulated wearing treatment shall be carried out by the following process.		P
8.3.2	Temperature conditioning		-
	Expose the particle filtering half masks to the following thermal cycle: a) for 24 h to a dry atmosphere of $(70 \pm 3) ^\circ \text{C}$ ; b) for 24 h to a temperature of $(-30 \pm 3) ^\circ \text{C}$ ;		P
8.3.3	Mechanical strength		-
	Conditioning shall be done in accordance with EN 143.		P
8.3.4	Flow conditioning		-
	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.	in accordance with 8.3.2.	P
8.4	Practical performance		-
8.4.1	General		-
	A total of 2 particle filtering half masks shall be tested: both as received.		P
8.4.2	Walking test		-
	The subjects wearing normal working clothes and wearing the particle filtering half mask shall walk at a regular rate of 6 km/h on a level course. The test shall be continuous, without removal of the particle filtering half mask, for a period of 10 min.		P
8.4.3	Work simulation test		-
	The particle filtering half mask shall be tested under conditions which can be expected during normal use. During this test the following activities shall be carried out in simulation of the practical use of the particle filtering half mask. The test shall be completed within a total working time of 20 min.	within a total working time of 20 min	P
8.5	Leakage		-
8.5.1	General test procedure		-

Clause	Requirement-Test	Result-Remark	Verdict
8.5.1.1	Total inward leakage		-
	A total of 10 test specimens shall be tested: 5 as received and 5 after temperature conditioning in accordance with 8.3.2.	in accordance with 8.3.2.	P
8.5.1.2	Test equipment		-
	The test atmosphere shall preferably enter the top of the enclosure through a flow distributor, and be directed downwards over the head of the test subject at a minimum flow rate of 0,12 m/s. The concentration of the test agent inside the effective working volume shall be checked to be homogeneous. The flow rate should be measured close to the subject' s head.		P
8.5.1.3	Test procedure		-
	Ask the test subjects to read the manufacturer' s fitting information and if more than one size of particle filtering half mask is manufactured, ask the test subject to select the size deemed by him to be the most appropriate. If necessary the test supervisor shall show the test subjects how to fit the particle filtering half mask correctly in accordance with the fitting information.		P
8.5.2	Method		-
8.5.2.1	Principle		-
	The subject wearing the particle filtering half mask under test walks on a treadmill over which is an enclosure		P
8.5.2.2	Test equipment		-
8.5.2.2.1	Aerosol generator		-
	The NaCl aerosol shall be generated from a 2 % solution of reagent grade NaCl in distilled water. An atomizer equivalent to the type described should be used. This requires an air flow rate of 100 l/min at a pressure of 7 bar. The atomizer and its housing shall be fitted into a duct through which a constant flow of air is maintained. It may be necessary to heat or dehumidify the air in order to obtain complete drying of the aerosol particles.		P
8.5.2.2.2	Test agent		-
	The mean NaCl concentration within the enclosure shall be $(8 \pm 4)$ mg/m <sup>3</sup> and the variation throughout the effective working volume shall be not more than 10 %. The particle size distribution shall be 0,02 $\mu$ m		P

Clause	Requirement-Test	Result-Remark	Verdict
	to 2 $\mu$ m equivalent aerodynamic diameter with a mass median diameter of 0,6 $\mu$ m.		
8.5.2.2.3	Flame photometer		-
	<p>A flame photometer shall be used to measure the concentration of NaCl inside the particle filtering half mask. Essential performance characteristics for a suitable instrument are:</p> <p>a) It should be a flame photometer specifically designed for the direct analysis of NaCl aerosol;</p> <p>b) It should be capable of measuring concentrations of NaCl aerosol between 15 mg/m<sup>3</sup> and 5 ng/m<sup>3</sup>;</p> <p>c) The total aerosol sample required by the photometer should not be greater than 15 l/min;</p> <p>d) The response time of the photometer, excluding the sampling system, should not be greater than 500 ms;</p> <p>e) It is necessary to reduce the response to other elements, particularly carbon, the concentration of which will vary during the breathing cycle. This will be achieved by ensuring that the band pass width of the interference filter is no greater than 3 nm and that all necessary side-band filters are included.</p>	Comply with the requirements	P
8.5.2.2.4	Sample selector		-
	<p>A system is required which will switch the sample to the photometer only during the inhalation phase of the respiratory cycle. During the exhalation phase clean air shall be fed to the photometer. The essential elements of such a system are:</p> <p>a) An electrically operated valve with a response time of the order of 100 ms. The valve should have the minimum possible dead space compatible with straight-through, unrestricted flow when open;</p> <p>b) A pressure sensor which is capable of detecting a minimum pressure change of approx. 0,05 mbar and which can be connected to a probe inserted in the cavity of the particle filtering half mask. The sensor shall have an adjustable threshold and be capable of differential signalling when the threshold is crossed in either direction. The sensor shall work reliably when subjected to the accelerations produced by the head movements of the subject;</p> <p>c) An interfacing system to actuate the valve in response to a signal from the pressure sensor;</p>		P



Clause	Requirement-Test	Result-Remark	Verdict
	d) timing device to record the proportion of the total respiratory cycle during which sampling took place.		
8.5.2.2.5	Sampling probe		-
	The probe shall be fitted securely in an airtight manner to the particle filtering half mask as near as possible to the centre line of the particle filtering half mask. A multiple hole sampling probe is strongly recommended.		P
8.5.2.2.6	Sample pump		-
	If no pump is incorporated into the photometer an adjustable flow pump is used to withdraw an air sample from the particle filtering half mask under test. This pump is so adjusted as to withdraw a constant flow of 1 l/min from the sample probe. Dependent on the type of photometer it may be necessary to dilute the sample with clean air.		P
8.5.2.2.7	Sampling of enclosure concentration		-
	The enclosure aerosol concentration is monitored during the tests using a separate sampling system, to avoid contamination of the particle filtering half mask sampling lines. It is preferable to use a separate flame photometer for this purpose.		P
8.5.2.2.8	Pressure detection probe		-
	A second probe is fitted near to the sample probe and is connected to the pressure sensor.		P
8.5.2.3	Expression of results		-
	The leakage P shall be calculated from measurements made over the last 100 s of each of the exercise periods to avoid carry over of results from one exercise to the other. $P(\%) = \frac{C_2}{C_1} \times \left( \frac{t_{IN} + t_{EX}}{t_{IN}} \right) \times 100$		P
	where C1 is the challenge concentration C2 is the measured mean concentration in the breathing zone of the test subject tIN is the total duration of inhalation tEX is the total duration of exhalation		-
8.6	Flammability		-
	A total of four particle filtering half masks shall be tested: two in the state as received and two after temperature conditioning in accordance with 8.3.2.	in accordance with 8.3.2.	P

Clause	Requirement-Test	Result-Remark	Verdict
8.7	Carbon dioxide content of the inhalation air		-
	A total of 3 particle filtering half masks shall be tested: all 3 as received.		P
8.8	Strength of attachment of exhalation valve housing		-
	A total of three particle filtering half masks shall be tested: one as received, one temperature conditioned in accordance with 8.3.2 and one after the test described for mechanical strength in EN 143		P
8.9	Breathing Resistance		-
8.9.1	Test samples and fixture		-
8.9.1.1	Valveless particle filtering half masks		-
	A total of 9 ~ valveless particle filtering™ half masks shall be tested: 3 as received, 3 after temperature conditioning in accordance with 8.3.2 and 3 after the test for simulated wearing in accordance with 8.3.1		P
8.9.1.2	Valved particle filtering half masks		-
	A total of 12 valved particle filtering half masks shall be tested: 3 as received, 3 after temperature conditioning in accordance with 8.3.2, 3 after the test for simulated wearing in accordance with 8.3.1 and 3 after the flow conditioning in accordance with 8.3.4.		P
8.9.2	Exhalation resistance		-
	Seal the particle filtering half mask on the Sheffield dummy head. Measure the exhalation resistance at the opening for mouth of the dummy head using the adapter shown in Figure 6 and a breathing machine adjusted to 25 cycles/min and 2.0 l/stroke or a continuous flow 160 l/min. Use a suitable pressure transducer.		P
8.9.3	Inhalation resistance		-
	Test the inhalation resistance at 30 l/min and 95 l/min continuous flow.		P
8.10	Clogging		-
8.10.1	Principle		-
	The test aerosol shall be dolomite. A total of 3 particle filtering half masks shall be tested: 1 as received and 2 after temperature conditioning in accordance with 8.3.2.		P
8.10.2	Test equipment		-
	A scheme of a typical apparatus is given in Figure 10. The working area of the test chamber has a suggested square section of 650 mm × 650 mm.		P

Clause	Requirement-Test	Result-Remark	Verdict
8.10.3	Test conditions		-
	Dust: DRB 4/15 dolomite		-
	The size distribution of dolomite dust is given in Table 3.	given in Table 3.	P
8.10.4	Test procedure		-
	Convey dust from the distributor to the dust chamber where it is dispersed into the air stream of 60 m <sup>3</sup> /h.		P
8.10.5	Assessment of clogging		-
	Following the exposure, measure the breathing resistance of the particle filtering half mask using clean air. Then measure the filter penetration in accordance with 8.11.	in accordance with 8.11.	P
8.11	Penetration of filter material		-
	The device shall be mounted in a leaktight manner on a suitable adaptor and subjected to the test(s), ensuring that components of the device that could affect filter penetration values such as valves and harness attachment points are exposed to the challenge aerosol.		P
9	Marking		P
9.1	Packaging		-
	The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.		P
9.1.1	The name, trademark or other means of identification of the manufacturer or supplier.		-
9.1.2	Type-identifying marking.		-
9.1.3	Classification The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D."	FFP2	P
9.1.4	The number and year of publication of this European Standard.		-
9.1.5	At least the year of end of shelf life. The end of shelf life may be informed by a pictogram as shown in Figure 12a, where yyyy/mm indicates the year and month.		P
9.1.6	The sentence 'see information supplied by the manufacturer', at least in the official language(s)		P

Clause	Requirement-Test	Result-Remark	Verdict
	of the country of destination, or by using the pictogram as shown in Figure 12b		
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.		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". !This letter shall follow the classification marking preceded by a single space.		P
9.2	Particle filtering half mask		-
	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.		-
9.2.2	Type-identifying marking.		-
9.2.3	The number and year of publication of this European Standard.		-
9.2.4	Classification The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D."	FFP2	P
9.2.5	If appropriate the letter D (dolomite) in accordance with clogging performance. This letter shall follow the classification marking preceded by a single space	see 9.2.4	-
9.2.6	Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.		P
10	Information to be supplied by the manufacturer		-
10.1	Information supplied by the manufacturer shall accompany every smallest commercial available package.		P
10.2	Information supplied by the manufacturer shall be at least in the official language(s) of the country of destination.		-
10.3	The information supplied by the manufacturer shall contain all information necessary for trained		P

Clause	Requirement-Test	Result-Remark	Verdict
	and qualified persons on		
	application/limitations; the meaning of any colour coding; checks prior to use; donning, fitting; use; maintenance (e.g. cleaning, disinfecting), if applicable; storage; the meaning of any symbols/pictograms used of the equipment.		P
10.4	The information shall be clear and comprehensible. If helpful, illustrations, part numbers, marking shall be added.		P
10.5	Warning shall be given against problems likely to be encountered, for example: fit of particle filtering half mask (check prior to use); it is unlikely that the requirements for leakage will be achieved if facial hair passes under the face seal; air quality (contaminants, oxygen deficiency); use of equipment in explosive atmosphere.		P
10.6	The information shall provide recommendations as to when the particle filtering half mask shall be discarded.		P
10.7	For devices marked "NR", a warning shall be given that the particle filtering half mask shall not be used for more than one shift."		P

Clause	Requirement-Test	Result-Remark	Verdict
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Table 1 — Penetration of filter material

Classification	Maximum penetration of test aerosol (%)	
	Sodium chloride test 95 l/min % max.	Paraffin oil test 95 l/min % max.
FFP1	20	20
FFP2	6	6
FFP3	1	1

Table 2 — Breathing resistance

Classification	Maximum permitted resistance (mbar)		
	inhalation		exhalation
	30 l/min	95 l/min	160 l/min
FFP1	0,6	2,1	3,0
FFP2	0,7	2,4	3,0
FFP3	1,0	3,0	3,0

Clause	Requirement-Test	Result-Remark	Verdict
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Table 3 — Size distribution of dolomite dust

Coulter counter		Sedimentation analysis	
Size (equivalent spherical diameter)	% Number particles oversize	Size (Stokes diameter)	% weight oversize
$\mu\text{m}$		$\mu\text{m}$	
0,7	100	1	99,5
1	80	2	97,5
2	30	3	95
3	17	5	85
5	7	8	70
		10	50
9	2	12	26
		14	10
12	1	18	1

# Photo of Sample





# **EC Declaration of conformity**

**Council Directive R 2016/425 (Regulation on Personal Protective Equipment)**

**Medical Device Branch of Zhangzhou Easepal Industrial Co., Ltd  
4th Floor of Building #7, No.228, Jiaosong Road, Taiwanese Investment Zone,  
Zhangzhou, Fujian, China**

Certify that the product described is in conformity with the Directive R 2016/425  
as amended

**Product Name:**

**Personal protective mask**

**Item No:**

**D13003**

The product has been assessed by the application of the following standards:

**EN 149:2001+A1:2009**

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Issue place and date

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Company stamp and Signature of authorized personnel

# Notice

1. This test report shall be invalidation without the cachet of the testing laboratory.
2. This copied report shall be invalidation without sealed the cachet of the testing laboratory.
3. This report shall be invalidation without tester signature.
4. This altered report shall be invalidation.
5. Client shall put forward demurrer within 15 days after received report.  
The testing laboratory shall refuse disposal if exceeded the time limit.
6. The test results presented in this report relate only to the object tested.