



Centre d'Essais de Fontaine
17, Boulevard Paul Langevin
38600 FONTAINE - France
Tél. +33.(0)4.76.53.52.22
Fax +33.(0)4.76.53.32.40
lab38apr@apave.com

Basaran Is Elbiseleri.Ve Is Guvenligi
Ekipmanlari Sanayi Ticaret Ltd.Sti. -
Merkez Mh.Ataturk
Cd: No:49 Orhanli
Tuzla
ISTAMBUL
Turkey

CE TYPE EXAMINATION REPORT

PPE DIRECTIVE 89/686/EEC - Article 10

Respiratory protective device

Report n°	11.7.0058
Technical referential	EN 149:2001 + A1 : 2009
Type of device	PPE category III Filtering half mask to protect against particles
Class	FFP2 NR
Trade Mark	ERA
Model	1200

Fontaine, the 21st December 2011

Report in 2 copies; send to the address above, for the attention of EROL MEMİŞ.

This report includes 14 pages

The PPE technical manager



Olivier VILA COBARSİ

Summary

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2. Use of the report
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1.Introduction - Description of the service

This report concerns a PPE category III – filtering half mask to protect against particles as defined in § 4 of EN 149:2001 + A1 : 2009

Its purpose is to assess the conformity of the filtering half mask to protect against particles with the European Directive 89/686/EEC of 21 December 1989 "Personal Protective Equipment" transposed into French labour code, with a view to be placed on the European market exclusively.

The examination was conducted in accordance with purchase order placed by Basaran Is Elbiseleri.Ve Is Guvenligi Ekipmanlari Sanayi Ticaret Ltd.Sti.

Company: Basaran Is Elbiseleri.Ve Is Guvenligi Ekipmanlari Sanayi Ticaret Ltd.Sti. - Merkez Mh.Ataturk – Cd: No:49 Orhanli – Tuzla – ISTAMBUL – Turkey

2.Use of the report

This report only concerns the equipment identified in clause 3 and described in clause 6.

Only an integral reproduction of this report is authorized.

The manufacturer, or his representative, commits himself not to use this report for equipment that is not strictly identical to the equipment covered by this report.

3.Identification of the equipment

3.1.Manufacturer – Manufacturing place – Place on the market

Basaran Is Elbiseleri.Ve Is Guvenligi Ekipmanlari Sanayi Ticaret Ltd.Sti. - Merkez Mh.Ataturk – Cd: No:49 Orhanli – Tuzla – ISTAMBUL – Turkey

3.2.Tested equipment

Following equipment has been tested:

Class: **FFP2 NR**

Trade mark: **ERA**

Model: **1200**

A CE type examination certificate is awarded for this equipment.

3.3.Equivalences

No equivalence

3.4.Other trade name

No other trade name

4.Conditions for use of the equipment

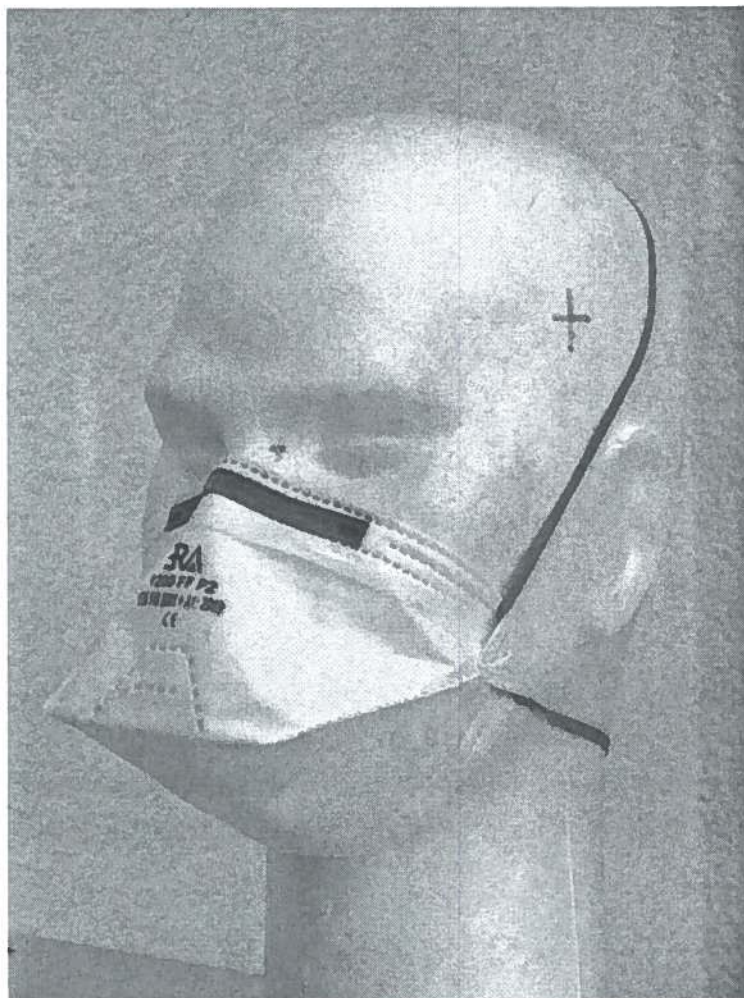
This filtering half mask is intended to be used as respiratory protective devices to protect against particles except for escape purposes.

5.Reference specification

The assessment of conformity with Directive 89/686/EEC of 21 December 1989 "Personal Protective Equipment" was conducted taking also into account the provisions of European standard EN 149:2001 + A1:2009 " Respiratory protective devices – Filtering half masks to protect against particles".

6.Description of the equipment

6.1.Drawing





6.2.Description

Filtering half mask to protect against particles class FFP2 NR limited to single shift use only. It consists entirely of filter material and is designed with one nose slide and two self-adjusting head harnesses

6.3.Description of components

Detailed description of the equipment model 1210 in the manufacturing technical file dated on 15/12/2011 received on 21/12/2011 and edited by Basaran Is Elbiseleri.Ve Is Guvenligi Ekipmanlari Sanayi Ticaret Ltd.Sti.

6.4.Location of the CE marking

- * Notified body in charge of
manufactured PPE category III control (article 11): **APAVE SUDEUROPE SAS - France**
- * CE mark: **CE 0082**
- * Graphic of letters C and E: **Conform**
- * Height of mark: **6 mm**
- * Marking clear and permanent: **Conform**
- * Location of the marking: **Printed on the upper outside**

7. Correlation between the articles of Directive 89/686/EEC and the reference standard

The following table shows the correlation between the essential requirements of Directive 89/686/CEE of 21 December 1989 "Personal Protective Equipment " and the articles of the European standard EN 149:2001 + A1:2009 " Respiratory protective devices – Filtering half masks to protect against particles".

Directive 89/686/EEC Annex II	Clauses of the standard
1.1.1	5 ; 7.8 ; 7.9
1.1.2.1	5 ; 7.8 ; 7.9
1.1.2.2	7.8 ; 7.9
1.2.1	7.6
1.2.1.1	7.6 ; 7.7 ; 7.10 ; 7.11
1.2.1.2	7.8
1.2.1.3	7.8 ; 7.13
1.3.1	7.8 ; 7.13
1.3.2	7.8 ; 7.13 ; 7.15.2
1.4	10
2.1	7.13
2.3	7.14
2.4	9 ; 10
2.6	10
2.8	10
2.9	7.13 ; 7.18
2.12	9
3.10.1	7.6 ; 7.7 ; 7.8 ; 7.9 ; 7.12 ; 7.16 ; 7.17 ; 9 ; 10

WARNING: Other requirements and other EU Directives maybe applicable to the products falling within the scope of this European Standard.

8.Examination report

Article of the standard EN 149+A1	Content	Conformity*			Comments
		Yes	No	N-A	
Art. 7	Requirements				
Art 7.3	Visual inspection The visual inspection shall also include the marking and the information supplied by the manufacturer	✓			
Art 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.	✓			
Art 7.5	Material 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. After undergoing the simulated wearing treatment none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps. Three particle filtering half masks shall be tested. When conditioned, the particle filtering half mask shall not collapse. Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	✓			Date of test: 16/08/2011
Art 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. After cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class.			✓	Single use mask

Article of the standard EN 149+A1	Content	Conformity*			Comments
		Yes	No	N-A	
Art 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 can not be determined by the tests described elsewhere in this standard. Where practical performance tests show the apparatus has imperfections related to wearer's acceptance, the test houses shall provide full details of those parts of the practical performance tests which revealed these imperfections.	✓			Date of test: 26/10/2011 any imperfections determined
Art 7.8	Finish of parts Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs	✓			
Art 7.9 Art 7.9.1	Leakage 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. The total inward leakage consists of three components: face seal leakage, exhalation valve leakage(if exhalation valve fitted) and filter penetration. For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e.10 subjects x 5 exercises) for total inward leakage shall be not greater than 11% for FFP2 and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than 8% for FFP2	✓			Date of test: 26/10/2011 46 individual results ≤ 11% 9 averages ≤ 8%

Exercise	Test subject reference									
	1	2	3	4	5	6	7	8	9	10
a	0.24	0.84	1.94	0.19	1.07	0.22	10.46	3.75	1.09	1.83
b	0.26	0.62	1.25	1.12	3.94	0.16	11.99	3.33	1.16	5.43
c	0.33	0.44	2.09	0.69	1.52	0.18	16.21	4.91	1.56	4.56
d	0.25	0.36	0.60	0.09	0.17	0.11	14.41	2.82	1.08	2.29
e	0.35	0.93	1.05	0.35	0.73	0.14	16.65	3.93	0.88	2.78
average	0.29	0.63	1.38	0.49	1.48	0.16	13.90	3.75	1.15	3.38

Total inward leakage values in %

Article of the standard EN 149+A1	Content	Conformity*			Comments														
		Yes	No	N-A															
Art 7.9.2	Penetration of filter material The penetration of the filter of the particle filtering half mask shall meet the requirements of Table1. <table><tr><th rowspan="2">Classification</th><th colspan="2">Maximum penetration of test aerosol</th></tr><tr><th>Sodium chloride test 95 l/min % max.</th><th>Paraffin oil test 95 l/min % max.</th></tr><tr><td>FFP1</td><td>20</td><td>20</td></tr><tr><td>FFP2</td><td>6</td><td>6</td></tr><tr><td>FFP3</td><td>1</td><td>1</td></tr></table> Tableau 1 – Pénétration du matériau filtrant A total of 9 samples of particle filtering half masks shall be tested for each aerosol. Testing using the Penetration test according to EN 13274-7, shall be performed on: - 3 samples as received; - 3 samples after the simulated wearing treatment (SWT). Testing using the exposure test with a specified mass of test aerosol of 120 mg, and for particle filtering devices claimed to be re-usable additionally the Storage test, according to EN 13274-7, shall be performed: - for non-re-usable devices on 3 samples after the test for mechanical strength (MS) followed by temperature conditioning (TC). - for re-usable devices on 3 samples after the test for mechanical strength followed by temperature conditioning and followed by one cleaning (CLEAN) and disinfecting cycle according to the manufacturer's instruction.	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	✓			Date of test: 16/08/2011 <u>Tests results with paraffin oil :</u> Exposure tests : After MS, CT ≤ 2.89 % Penetration tests : As received ≤ 1.88 % After SWT ≤ 2.36 % <u>Tests results with Sodium Chloride :</u> Exposure tests : After MS, CT ≤ 1.52 % Penetration tests : As received ≤ 1.24 % After SWT ≤ 1.65 %
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																	
Art 7.10	Compatibility 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.	✓			Manufacturer statement														
Art 7.11	Flammability The material used shall not present a danger for the wearer and shall not be of highly flammable nature. When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5 s after removal from the flame. The particle filtering half mask does not have to be usable after the test.	✓			Date of test: 16/08/2011 The mask doesn't burn 5s after removal from the flame														

Article of the standard EN 149+A1	Content	Conformity*			Comments																						
		Yes	No	N-A																							
Art 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)	✓			Date of tests : 28/07/2011 CO ₂ ≤ 0.81 %																						
Art 7.13	Head harness The head harness shall be designed so that the particle filtering half mask can be donned and removed easily. The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the particle filtering half mask firmly in position and be capable of maintaining total inward leakage requirements for the device.	✓			Self-Adjusting harness																						
Art 7.14	Field of vision The field of vision is acceptable if determined so in practical performance tests	✓			See Art 7.7																						
Art 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 If an 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 that may be necessary for the particle filtering half mask to comply with 7.9. Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s. When the exhalation valve housing is attached to the face blank, it shall withstand axially a tensile force of 10 N applied for 10s.			✓ ✓ ✓ ✓	Without exhalation valve																						
Art 7.16	Breathing resistance The breathing resistances apply to valved and valveless particle filtering half masks and shall meet the requirements of Table 2. <table border="1"><thead><tr><th rowspan="3">Classification</th><th colspan="3">Maximum permitted resistance (mbar)</th></tr><tr><th colspan="2">inhalation</th><th>exhalation</th></tr><tr><th>30 l/min</th><th>95 l/min</th><th>160 l/min</th></tr></thead><tbody><tr><td>FFP1</td><td>0.6</td><td>2.1</td><td>3.0</td></tr><tr><td>FFP2</td><td>0.7</td><td>2.4</td><td>3.0</td></tr><tr><td>FFP3</td><td>1</td><td>3</td><td>3.0</td></tr></tbody></table> 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	3	3.0	✓			Date of tests: 19/10/2011 at 30l/min ≤ 0.40 mbar at 95l/min ≤ 1.27 mbar at 160l/min ≤ 1.87 mbar
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	3	3.0																								
Art 7.17	Clogging			✓	No requested																						
Art 7.18	Demountable parts All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.			✓																							

* The measurement uncertainties are not taken into account for the assessment of conformity.

Article of the standard EN 149+A1	Content	Conformity			Comments
		Yes	No	N-A	
Art. 9	Marking				
Art 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	✓			
Art 9.1.1	The name, trademark or other means of identification of the manufacturer or supplier	✓			
Art 9.1.2	Type-identifying marking	✓			
Art 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.	✓			
Art 9.1.4	The number and year of publication of this European Standard	✓			
Art 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 Figure12a, where yyyy/mm indicates the year and month.	✓			
Art 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 equivalent pictogram.	✓			
Art 9.1.7	The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram	✓			
Art 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.			✓	

Article of the standard EN 149+A1	Content	Conformity			Comments
		Yes	No	N-A	
Art. 9	Marking (continuation)				
Art 9.2	Particle filtering half mask Particle filtering half masks complying with this European Standard shall be clearly and durably marked with the following:	✓			
Art 9.2.1	The name, trademark or other means of identification of the manufacturer or supplier	✓			
Art 9.2.2	Type-identifying marking	✓			
Art 9.2.3	The number and year of publication of this European Standard	✓			
Art 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."	✓			
Art 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).			✓	
Art 9.2.6	Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified			✓	
Directive	CE Marking (CE + Notified body) The marking shall be clearly, durably and permanently marked by any mean without effect on material Legible and visible characters	✓ ✓ ✓			

Article of the standard EN 149+A1	Content	Conformity			Comments
		Yes	No	N-A	
	<i>Concerning the instruction for use: Only the English version has been checked. It is the responsibility of the manufacturer to supply the instruction for use in the official languages of the country of destination</i>				
Art. 10	Information to be supplied by the manufacturer				
Art 10.1	Information supplied by the manufacturer shall accompany every smallest commercial available package	✓			
Art 10.2	Information supplied by the manufacturer shall be at least in the official language(s) of the country of destination	✓			
Art 10.3	The information supplied by the manufacturer shall contain all information necessary for trained 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/pictogram used of the equipment	✓ ✓ ✓ ✓ ✓ ✓ ✓			
Art 10.4	The information shall be clear and comprehensible. If helpful, illustrations, part numbers, marking shall be added.	✓			
Art 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.	✓ ✓ ✓ ✓			
Art 10.6	The information shall provide recommendations as to when the particle filtering half mask shall be discarded.	✓			
Art 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.	✓			
Directive	Presence of name, address the manufacturer or supplier	✓			
	Presence of name, address and notified body number who have done CE type examination	✓			

9. Conclusion

The filtering half mask to protect against particles trade mark "**ERA**", model "**1200**" meets the basic requirements of European Directive 89/686 of 21 December 1989, "Personal Protective Equipment" relative to the design of the product examined and transposed into French law by the relevant articles of French labour code.

The assessment of conformity takes into account the compliance of filtering half mask to protect against particles with the provisions of European standard EN 149:2001 + A1 : 2009 and with the conformity of manufacturer's technical file.

Consequently, a CE type examination certificate is issued for this equipment:

Number of CE Type examination certificate: 0082/1585/079/12/11/0535