

KOLMI-HOPEN SASU
Boulevard de la Chanterie
49124 ST BARTHÉLEMY D'ANJOU
France

EU TYPE EXAMINATION REPORT
PPE REGULATION 2016/425 – ANNEX V
Respiratory protective device

Report n°	19.0145
Technical referential	EN 149:2001 + A1:2009
Type of device	PPE category III Filtering half mask to protect against particles
Class	FFP2 NR D
Trade mark	MEDICOM
Model	SAFE+OXYGEN FFP2 NR D
References	2092-LM (Lime color) 2092S-LM (Lime color - Individually packed) 2092-OR (Orange color) 2092S-OR (Orange color - Individually packed) 2092-WH (White color) 2092S-WH (White color - Individually packed) 2092-BL (Blue color) 2092S-BL (Blue color - Individually packed) 2092-GR (Green color) 2092S-GR (Green color - Individually packed) 2092-PK (Pink color) 2092S-PK (Pink color - Individually packed) 2092-YL (Yellow color) 2092S-YL (Yellow color - Individually packed) 2092-LV (Lavender color) 2092S-LV (Lavender color - Individually packed)

Fontaine, the 27/02/2019,

Report sent for the attention of Yannick CHEVALIER to the email address ychevalier@kolmi-hopen.com.

This report includes 15 pages

The PPE technical manager
Immaterial original



ANAÏS JAVET VIALA

Validation électronique

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1.Introduction - Description of the service

This report concerns PPE category III – Filtering half mask to protect against particles as defined in EN 149:2001 + A1:2009 "Respiratory protective device – Filtering half mask to protect against particles".

Its purpose is to assess the conformity of the PPE with the PPE REGULATION 2016/425, with a view to be placed on the European market exclusively.

The examination was conducted in accordance with purchase order on 21/01/2019 placed by KOLMI-HOPEN SASU.

Company: KOLMI-HOPEN SASU - Boulevard de la Chanterie - 49124 ST BARTHÉLEMY D'ANJOU - France

2.Use of the report

This report only concerns the equipment identified in clause 4 and described in clause 7.

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.Economical operator(s)

KOLMI-HOPEN SASU - Boulevard de la Chanterie - 49124 ST BARTHÉLEMY D'ANJOU - France

4.Identification of the equipment

Class: FFP2 NR D
Trade mark: MEDICOM
Model: SAFE+OXYGEN FFP2 NR D
References: 2092-LM – *Specificity*: Lime color
2092-OR – *Specificity*: Orange color
2092-WH – *Specificity*: White color
2092-BL – *Specificity*: Blue color
2092-GR – *Specificity*: Green color
2092-PK – *Specificity*: Pink color
2092-YL – *Specificity*: Yellow color
2092-LV – *Specificity*: Lavender color
2092S-LM – *Specificity*: Lime color – Individually packed
2092S-OR – *Specificity*: Orange color – Individually packed
2092S-WH – *Specificity*: White color – Individually packed
2092S-BL – *Specificity*: Blue color – Individually packed
2092S-GR – *Specificity*: Green color – Individually packed
2092S-PK – *Specificity*: Pink color – Individually packed
2092S-YL – *Specificity*: Yellow color – Individually packed
2092S-LV – *Specificity*: Lavender color – Individually packed

An EU type examination certificate is awarded for these equipment.

5.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.

6.Reference specification

The assessment of conformity with Regulation 2016/425 of 9th march 2016 "Personal Protective Equipment" was conducted taking into account the provisions of European standard EN 149:2001 + A1:2009 "Respiratory protective device – Filtering half mask to protect against particles".

7. Technical Documentation

7.1. Identification

Identification of the assessed Technical Documentation:

1. Authorized representative – Company: Yannick CHEVALIER – KOLMI-HOPEN SASU
2. Commitment signature date: 21/02/2019
3. Technical Documentation reference: Not applicable

7.2. Drawing



7.3.Description

Filtering half mask to protect against particles class FFP2 NR D without exhalation valve, limited to single shift use only, and complying with the optional clogging requirements. The half mask is foldable, designed with a noseclip in steel and polypropylene and two self-adjusting head harness in synthetic rubber. The filter media is composed of two meltblown and spunbond composite polypropylene layers and one layer of spunbond polypropylene.

7.4.Description of components

Detailed description of components in the Technical Documentation.

7.5.CE Marking

× Notified body in charge of assessment control to article 19c) of PPE regulation (module C2 or D):

APAVE SUDEUROPE SAS - France

× CE mark:

CE 0082

× Graphic of letters C and E:

Conform

× Height of mark:

9mm

× Marking clear and permanent:

Conform

× Location of the marking:

Printed on the front of the mask

7.6.Packaging

Month and year of manufacture and month and year of obsolescence are indelibly and unambiguously marked on the packaging.

8. Correlation between the articles of PPE Regulation 2016/425 and the reference standard

The following table shows the correlation between the essential health and safety requirements of Regulation 2016/425 of 9th march 2016 "Personal Protective Equipment" and the articles of the European standard EN 149:2001 + A1:2009 "Respiratory protective device – Filtering half mask to protect against particles".

PPE Regulation 2016/425 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.

9.Examination report

9.1.Preliminary remark

The manufacturer certified he has not made any changes to the PPE since the EU type examination except secondary modifications listed in its technical documentation for review. This evaluation takes into account the EU type examination results from APAVE file n° 19.0030.

9.2.Requirements

Article of the standard EN 149+A1	Content	Conformity*			Comments
		Yes	No	N-A	
Art. 7	Requirements				
Art 7.1	Visual inspection The visual inspection shall also include the marking and the information supplied by the manufacturer	✓ ¹			
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.	✓ ¹			
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.	✓ ¹			
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.			✓ ¹	

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

¹ The evaluation results are detailed in the original EU type examination file as defined in paragraph 9.1

Article of the standard EN 149+A1	Content	Conformity*			Comments
		Yes	No	N-A	
Art 7.7	<p>Practical performance</p> <p>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. 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.</p> <p>Here are the comments of the test subjects:</p> <p>a) head harness comfort</p> <p>b) security of fastenings</p> <p>c) field of vision</p> <p>d) any other comments reported by the wearer on request</p>	<p>✓¹</p> <p>✓¹</p> <p>✓¹</p> <p>✓¹</p>			<p>No comment</p> <p>No comment</p> <p>No comment</p> <p>No comment</p>
Art 7.8	<p>Finish of parts</p> <p>Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs</p>	<p>✓¹</p>			
Art 7.9 Art 7.9.1	<p>Leakage</p> <p>Total inward leakage</p> <p>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:</p> <p style="text-align: center;">11 % for FFP2</p> <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> <p style="text-align: center;">8 % for FFP2</p>	<p>✓¹</p>			

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Article of the standard EN 149+A1	Content	Conformity*			Comments														
		Yes	No	N-A															
Art 7.9.2	<p>Penetration of filter material The penetration of the filter of the particle filtering half mask shall meet the requirements of Table1.</p> <p>Tableau 1 – Penetration of filter material</p> <table border="1"> <thead> <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> </thead> <tbody> <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> </tbody> </table>	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	✓ ¹			Manufacturer statement
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	<p>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.</p>	✓ ¹																	
Art 7.11	<p>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.</p>	✓ ¹																	
Art 7.12	<p>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)</p>	✓ ¹																	
Art 7.13	<p>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.</p>	✓ ¹			Self-Adjusting harness														

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

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Article of the standard EN 149+A1	Content	Conformity*			Comments																					
		Yes	No	N-A																						
Art 7.14	Field of vision The field of vision is acceptable if determined so in practical performance tests	✓ ¹			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.			✓ ¹ ✓ ¹ ✓ ¹ ✓ ¹																						
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.	✓ ¹																								
	<p>Tableau 2 – Breathing resistance</p> <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>inhalation</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>	Classification	Maximum permitted resistance (mbar)			inhalation		inhalation	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			
Classification	Maximum permitted resistance (mbar)																									
	inhalation		inhalation																							
	30 l/min	95 l/min	160 l/min																							
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* The measurement uncertainties are not taken into account for the assessment of conformity.

¹ The evaluation results are detailed in the original EU type examination file as defined in paragraph 9.1

Article of the standard EN 149+A1	Content	Conformity*			Comments
		Yes	No	N-A	
Art 7.17	Clogging				
Art 7.17.1	General For single shift use devices, the clogging test is an optional test. For re-usable devices the test is mandatory. Devices designed to be resistant to clogging, shown by a slow increase of breathing resistance when loaded with dust, shall be subjected to the treatment described in 8.10. The specified breathing resistance shall not be exceeded before the required dust load of 833 mg.h/m ³ is reached	✓ ¹			
Art 7.17.2	Breathing resistance				
Art 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 ; at 95 l/min continuous flow The exhalation resistance shall not exceed 3 mbar at 160 l/min continuous flow	✓ ¹		✓ ¹ ✓ ¹	
Art 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	✓ ¹		✓ ¹ ✓ ¹	
Art 7.17.3	Filter penetration 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.	✓ ¹			
Art 7.18	Demountable parts All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.			✓ ¹	

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

¹ The evaluation results are detailed in the original EU type examination file as defined in paragraph 9.1.

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	✓ ¹			
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.	✓ ¹ ✓ ¹		✓ ¹	
Art 9.1.4	The number and year of publication of this European Standard	✓ ¹			
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.	✓ ¹			
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.	✓ ¹			
Art 9.1.7	The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram	✓ ¹			
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.	✓ ¹			

¹ The evaluation results are detailed in the original EU type examination file as defined in paragraph 9.1.

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	✓ ¹			
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."	✓ ¹ ✓ ¹		✓ ¹	
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).	✓ ¹			
Art 9.2.6	Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified			✓ ¹	
Regulation	CE Marking (CE + Notified body in charge of module C2 or D) The CE marking shall be affixed visibly, legibly and indelibly to the PPE. For PPE subject to ageing: the month and year of manufacture and/or, if possible, the month and year of obsolescence must be indelibly and unambiguously marked on each item of PPE placed on the market and on its packaging Name and address of the manufacturer	✓ ¹ ✓ ¹ ✓ ¹			Address on the packaging and the Instructions for Use

¹ The evaluation results are detailed in the original EU type examination file as defined in paragraph 9.1.

Article of the standard EN 149+A1	Content	Conformity			Comments
		Yes	No	N-A	
	<i>Concerning the instruction for use: Only the French 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	✓ ¹			
Art 10.2	Information supplied by the manufacturer shall be at least in the official language(s) of the country of destination	✓ ¹			
Art 10.3	The information supplied by the manufacturer shall contain all information necessary for trained and qualified persons on:	✓ ¹			
	— application/limitations ;	✓ ¹			
	— the meaning of any colour coding ;			✓ ¹	
	— checks prior to use ;	✓ ¹			
	— donning, fitting ;	✓ ¹			
	— use ;	✓ ¹			
	— maintenance (e.g. cleaning , disinfecting),if applicable;			✓ ¹	
	— storage ;	✓ ¹			
	— the meaning of any symbols/pictogram used of the equipment	✓ ¹			
Art 10.4	The information shall be clear and comprehensible. If helpful, illustrations, part numbers, marking shall be added.	✓ ¹			
Art 10.5	Warning shall be given against problems likely to be encountered, for example:	✓ ¹			
	— fit of particle filtering half mask (check prior to use);	✓ ¹			
	— it is unlikely that the requirements for leakage will be achieved if facial hair passes under the face seal;	✓ ¹			
	— air quality (contaminants, oxygen deficiency);	✓ ¹			
	— use of equipment in explosive atmosphere.	✓ ¹			
Art 10.6	The information shall provide recommendations as to when the particle filtering half mask shall be discarded.	✓ ¹			
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.	✓ ¹			
Regulation	Presence of :				
	Name and address of the manufacturer	✓			
	Name, address and identification number of the notified body or bodies involved in the conformity assessment of the PPE (module B and module C2 or D)	✓ ¹			
	EU declaration of conformity or the internet address where the EU declaration of conformity can be accessed	✓ ¹			

¹ The evaluation results are detailed in the original EU type examination file as defined in paragraph 9.1.

10. Conclusion

The PPE category III – Filtering half mask to protect against particles identified in paragraph 4 meets the Essential Health and Safety Requirements of PPE Regulation 2016/425 of 9th march 2016.

The assessment of conformity takes into account the compliance of the PPE with the provisions of European standard EN 149:2001 + A1:2009, and with the conformity of manufacturer's technical documentation.

Consequently, an EU type examination certificate is issued for these equipment:

Class: FFP2 NR D
Trade Mark: MEDICOM
Model: SAFE+OXYGEN FFP2 NR D
References: 2092-LM – *Specificity*: Lime color
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Number of EU Type examination certificate: 0082/1467/079/02/19/0212

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