



In enforcement of Regulation 2016/425 of the European Parliament and of the Council of 9th March 2016 on Personal Protective Equipment and repealing the Directive 89/686/EEC and in compliance with the Module B Certification Scheme of Apave 'M.MEPI.45' in force,
En exécution du Règlement 2016/425 du Parlement Européen et du Conseil du 9 mars 2016 relatif aux Equipements de Protection Individuelle et abrogeant la Directive 89/686/CEE et en respect du Programme de Certification Module B de l'Apave 'M.MEPI.45' en vigueur,

APAVE Sudeurope SAS, notified body identified under number 0082, awards the
APAVE Sudeurope SAS, organisme notifié identifié sous le numéro 0082, attribue l'

EU TYPE-EXAMINATION CERTIFICATE

Attestation d'examen UE de type

N° 0082/3857/079/02/21/0094

The following PPE type complies with the applicable essential health and safety requirements
Le type de l'EPI suivant est conforme aux exigences essentielles de santé et de sécurité applicables

PPE: PPE category III – Filtering half mask to protect against particles with and without exhalation valve

EPI : *EPI de catégorie III – Demi-masque filtrant contre les particules avec et sans soupape expiratoire*

Type: **FFP2 NR**
Type

Trademark: EFAS PROTECT
Marque commerciale

This certificate is awarded to the 2 following references:

La présente attestation est attribuée aux 2 références suivantes :

- **SA1500** – Specificity : valveless
Spécificité : sans valve
- **SA1510** – Specificity : with valve
Spécificité : avec valve

Manufacturer: AEREM INDUSTRY CO LTD - Workshop No.54 - Road 1-7 - Long Thanh IZ - TAM
Fabricant AN COMMUNE - Long Thanh District - Dong Nai Pr - Vietnam

Authorised representative: Aeremn Industry Sp. Zo.o.- Ul.Lubczynska 6F 70-895 SZCZECIN - Poland
Mandataire

Description: Filtering half mask to protect against particles class FFP2 NR with or without exhalation valve in polypropylene and rubber for single shift use only. The half mask is foldable with a vertical fold flat shape, designed with a noseclip in high-density polyethylene iron platine zinc and two self-adjusting ear loop in nylon and spandex. The filter media is composed of three layers in polypropylene and electret masterbatch and one layer in polyethylene ethylene-propylene sidebyside (detailed description in EU type examination report 20.1900).

Description : *Demi-masque filtrant contre les particules classe FFP2 NR avec ou sans soupape expiratoire en polypropylène et caoutchouc à usage unique. Le demi-masque est de forme plate à pliage verticale, conçu avec une barrette nasale en haute densité polyéthylène et deux brides auto-réglables en nylon et spandex portées derrière les oreilles. Le média filtrant est composé de trois couches en polypropylène et une couche en polyéthylène éthylène-propylène sidebyside (description détaillée dans le rapport d'examen UE de type 20.1900).*

Technical referential in use: EN 149 : 2001 + A1 : 2009
Référentiel technique utilisé

Date of signature (day/month/year): 11/02/2021
Date de signature (jour/mois/année)

Date of issue (day/month/year): 11/02/2021
Date de délivrance (jour/mois/année)

Date of renewal (day/month/year): first edition
Date de renouvellement (jour/mois/année) 1^{ère} édition

Date of expiry (day/month/year): 11/02/2026
Date d'expiration (jour/mois/année)

PPE Certification Manager
Le Responsable de la Certification EPI
Immaterial original

 
VILA COBARRI
Validation électronique



Accréditation N° 5-0596
Scope available on
Portée disponible sur
www.cofrac.fr

Apave Sudeurope SAS
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17, Boulevard Paul Langevin
38600 FONTAINE - France
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For category III PPE, the certificate shall only be used in conjunction with one of the conformity assessment procedures referred in point c) of Article 19
Pour les EPI de catégorie III, l'attestation ne doit être utilisée qu'en liaison avec l'une des procédures d'évaluation de la conformité visées à l'article 19, point c).
The manufacturer shall inform the notified body of all modifications to the approved type and of all modifications of the technical documentation that may affect the conformity of the PPE with the applicable essential health and safety requirements or the conditions for validity of that certificate (article 7.2 – annex V)
Le fabricant informe l'organisme notifié de toutes les modifications du type approuvé et de toutes les modifications de la documentation technique qui peuvent remettre en cause la conformité de l'EPI aux exigences essentielles de santé et de sécurité applicables ou les conditions de validité de cette attestation (article 7.2 – annexe V)

This certificate includes one page - Cette attestation comporte une page



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AEREM INDUSTRY CO LTD
Workshop No.54 - Road 1-7 - Long Thanh IZ
TAM AN COMMUNE - Long Thanh District - Dong
Nai Province
Vietnam

PPE REGULATION 2016/425 – ANNEX V
MODULE B – EU TYPE EXAMINATION
ASSESSMENT REPORT

Respiratory protective device

Report n° **20.1900** - English version
Technical referential **EN 149 : 2001 + A1 : 2009**
Type of device **PPE category III**
Filtering half mask to protect against particles
with and without exhalation valve
Class **FFP2 NR**
Trade mark **EFAS PROTECT**
References **SA1500** – Specificity : valveless
SA1510 – Specificity : with breathing valve

Fontaine, the 11/02/2021

Report sent for the attention of Marina BERNARD and Hadrien ROUBERT to the email addresses below: mbernard@aerem.com and hroubert@aerem.com

This report includes 17 pages

The technical assessment manager
Immaterial original


RASOLOFOJAINA Yélanie

Validation électronique

M.MEPI.324.V1

Summary

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

This assessment report concerns PPE category III – Filtering half mask to protect against particles with and without exhalation valve as defined in EN 149 : 2001 + A1 : 2009.

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 assessment was conducted in accordance with purchase order signed on 24/11/2020 placed by Aerem Industry Sp. Zo.o. for the count of AEREM INDUSTRY CO LTD.

Company: AEREM INDUSTRY CO LTD - Workshop No.54 - Road 1-7 - Long Thanh IZ - TAM AN COMMUNE - Long Thanh District - Dong Nai Province - Vietnam

2.Use of the report

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

Only an integral reproduction of this assessment report is authorized.

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

3.Economical operator(s)

Manufacturer and manufacturing site : AEREM INDUSTRY CO LTD - Workshop No.54 - Road 1-7
Long Thanh IZ - TAM AN COMMUNE Long Thanh District
Dong Nai Province – Vietnam

Authorized representative : Aerem Industry Sp. Zo.o.- Ul.Lubczynska 6F 70-895 SZCZECIN - Poland

4.Identification of the equipment

Class: FFP2 NR
Trade mark: EFAS PROTECT
Reference: SA1500 – Specificity : valveless

Class: FFP2 NR
Trade mark: EFAS PROTECT
Reference: SA1511 – Specificity : with breathing valve

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: Hadrien ROUBERT - AEREM INDUSTRY CO LTD
2. Commitment signature date: 15/12/2020
3. Technical Documentation reference: 20.1900

7.2. Drawing



Reference SA1501



Reference SA1510

7.3. Description

Filtering half mask to protect against particles class FFP2 NR with or without exhalation valve in polypropylene and rubber for single shift use only. The half mask is foldable with a vertical fold flat shape, designed with a noseclip in high-density polyethylene iron platine zinc and two self-adjusting ear loop in nylon and spandex. The filter media is composed of three layers in polypropylene and electret masterbatch and one layer in polyethylene ethylene-propylene sidebyside.

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: **8 mm**

× Marking clear and permanent: **Conform**

× Location of the marking: **Inkjet printed on the external part of the mask**

7.6. Packaging

Month and year of obsolescence is 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

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	✓			Date of test: 08/12/2020
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: 07/01/2021
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.			✓	

* 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 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>	✓			Date of test: 15/01/2021 any imperfections determined
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>	✓			No comment No comment No comment No comment

* 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 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.</p> <p>The total inward leakage consists of three components: face seal leakage, exhalation valve leakage (if exhalation valve fitted) and filter penetration.</p> <p>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>Date of test: 15/01/2021</p> <p>Without valve : 50 results ≤ 11% 10 averages ≤ 8%</p> <p>With valve : 48 results ≤ 11% 9 averages ≤ 8%</p>

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

Exercise	Half mask without valve									
	Test subject reference									
	1	2	3	4	5	6	7	8	9	10
Walk	0,2	0,2	0,2	1,3	0,6	0,3	0,6	7,3	1,2	0,7
Left-Right	0,2	0,7	1,1	1,1	1,8	0,6	1,0	5,5	3,6	3,5
Up-Down	1,2	0,9	1,0	2,2	1,4	1,0	1,0	9,3	7,3	4,1
Alphabet	0,7	0,9	1,7	2,5	0,7	1,6	1,9	4,3	4,2	5,7
Walk	0,5	0,9	1,4	0,9	0,5	1,0	1,2	8,0	5,5	6,9
average	0,6	0,7	1,1	1,6	1,0	0,9	1,1	6,9	4,4	4,2

* Total inward leakage values in %

Exercise	Half mask with valve									
	Test subject reference									
	11	12	13	14	15	16	17	18	19	20
Walk	0,4	1,4	0,4	0,3	0,7	0,2	8,1	0,9	2,8	0,1
Left-Right	0,6	1,5	1,8	0,1	1,5	0,4	9,1	2,6	4,9	0,2
Up-Down	0,4	1,6	2,3	0,2	2,8	0,5	12,6	2,3	7,4	0,7
Alphabet	0,2	1,5	4,4	0,2	4,0	0,5	9,4	3,3	5,0	0,5
Walk	0,2	3,3	2,7	0,2	2,4	0,4	13,0	2,6	6,9	0,3
average	0,4	1,9	2,3	0,2	2,3	0,4	10,4	2,3	5,4	0,4

* Total inward leakage values in %

Article of the standard EN 149+A1	Content	Conformity*			Comments														
		Yes	No	N-A															
Art 7.9.2	<p>Penetration of filter material</p> <p>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	✓			Date of test: 07/01/2021 All tests were carried out on half mask with exhalation valve
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																	

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

Paraffin oil penetration of filter material tests results (%)

Conditioning	AR			SWT		
Penetration (3min)	0,59	0,67	0,74	0,88	0,89	0,84

Conditioning	MS+TC		
Exposure (120mg)	3,19	3,87	3,22

Sodium chloride penetration of filter material tests results (%)

Conditioning	AR			SWT		
Penetration (3min)	0,21	0,36	0,21	0,28	0,41	0,40

Conditioning	MS+TC		
Exposure (120mg)	0,37	0,43	0,21

As Received (AR), Simulated Wearing Treatment (SWT), Mechanical Strength (MS), Temperature Conditioning (TC)

Article of the standard EN 149+A1	Content	Conformity*			Comments								
		Yes	No	N-A									
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: 07/01/2021 The mask doesn't burn 5s after removal from the flame								
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 test: 05/01/2021 CO ₂ (%) <table border="1"> <thead> <tr> <th colspan="2">Without valve</th> </tr> </thead> <tbody> <tr> <td>0,62</td> <td>0,64</td> </tr> <tr> <th colspan="2">With valve</th> </tr> <tr> <td>0,63</td> <td>0,65</td> </tr> </tbody> </table>	Without valve		0,62	0,64	With valve		0,63	0,65
Without valve													
0,62	0,64												
With valve													
0,63	0,65												
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 ear loops								
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.	✓ ✓ ✓			Ref SA 1510 Date of test: 06/01/2021 Date of test: 06/01/2021								

* 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 7.16	<p>Breathing resistance</p> <p>The breathing resistances apply to valved and valveless particle filtering half masks and shall meet the requirements of Table 2.</p> <p style="text-align: center;">Tableau 2 – Breathing resistance</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <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>	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 test: 04/01/2021
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																								

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

Breathing resistance tests results

Conditioning	AR				SWT			
	Without valve	Without valve	With valve	With valve	Without valve	Without valve	With valve	With valve
Half mask								
at 30l/min	0,31	0,30	0,33	0,32	0,30	0,32	0,34	0,34
at 95l/min	1,06	1,06	1,13	1,13	1,08	1,10	1,18	1,17
at 160l/min	1,53	1,51	1,61	1,50	1,62	1,58	1,64	1,58

Values in mbar

Conditioning	TC				300l/min during 30s Art 7.15		
	Without valve	Without valve	With valve	With valve	With valve	With valve	With valve
Half mask							
at 30l/min	0,30	0,34	0,33	0,32	0,31	0,33	0,36
at 95l/min	0,99	1,25	1,18	1,11	1,18	1,20	1,20
at 160l/min	1,47	1,65	1,57	1,55	1,68	1,64	1,66

Values in mbar

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				
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				
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				
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.				
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			✓	
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 ; Type, batch or serial number or other means of identification	✓ ✓ ✓ ✓ ✓			

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: <ul style="list-style-type: none"> — 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: <ul style="list-style-type: none"> — 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.	✓			
Regulation	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) ;	✓			
	EU declaration of conformity or the internet address where the EU declaration of conformity can be accessed ;	✓			
	The risk against which the PPE is designed to protect ;	✓			
	The reference to this Regulation	✓			
	The references to the relevant harmonised standard(s) used, including ;	✓			
	The date of the standard(s), or references to the other technical specifications used ;	✓			

10. Conclusion

The PPE category III – Filtering half mask to protect against particles with and without exhalation valve 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.

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