

Centre d'Essais et de certification de
Fontaine
17, Boulevard Paul Langevin
38600 FONTAINE - France
Tél. +33.(0)4.76.53.52.22

**Ramat Hakovesh, 1
4493000
Israel**

**UE TYPE EXAMINATION REPORT
PPE REGULATION – ANNEX V
Respiratory protective device**

Report n°	17.0416
Technical referential	Relevant requirements of EN 403:2004 and special requirements
Type of device	PPE category III Particles filtering device with hood for escape
Trade mark	
Model	4NE1

Fontaine, the 22/01/2018

Report sent for the attention of Ilan NIR to the email address

This report includes 13 pages.

The PPE technical manager
Olivier Vila Cobarsi
Immaterial original

Document original immatériel



7.3. Description

Particles filtering device with hood for escape. Air enters the latex hood via the eye area through two non separable particles filters without inhalation valve. Then, the air passes to the nose and mouth area of the hood via an inner half mask in silicon equipped with two rubber inhalation valves. The exhaled air flows back directly to the ambient atmosphere via one rubber exhalation valve. The hood is equipped with a eyepiece in ETFE copolymer and an external elastic band to maintain the inner half mask in place during the use. For single shift use. Before use, the hood is protected in a sealed pocket.

7.4. Description of components

Detailed description of components in the Technical Documentation.

7.5. Marking

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

ITALCERT SRL - Italy

× CE mark: **CE 0426**

× Graphic of letters C and E: **Conform**

× Height of mark: **10 mm**

× Marking clear and permanent: **Conform**

× Location of the marking: **On the packaging**

9.Examination report

9.1.Preliminary remark

The manufacturer certified he has not made any changes to the PPE since the EC type examination excepting secondary modifications listed in its simplified technical modification. This evaluation takes into account the CE type examination results from APAVE file n° 17.7.0102 and possible attached files.

9.2.Articles of the standard EN 403

Article of the standard EN 403	Content	Conformity*			Comments
		Yes	No	N-A	
Art. 6	Requirements				
Art 6.3	Design				
	The apparatus shall be sufficiently robust to withstand the rough usage it is likely to receive in service.	✓ ¹			
	The apparatus shall be designed so that there are no protruding parts or sharp edges likely to be caught on projections in narrow passages.	✓ ¹			
	No part of the apparatus likely to be in contact with the wearer shall have sharp edges or burrs.	✓ ¹			
	The apparatus shall be designed to ensure its full function in any orientation.	✓ ¹			
Art 6.4	Materials				
	Materials which come into direct contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.	✓ ¹			Manufacturer statement
	All metallic parts shall be corrosion-resistant or protected against corrosion e.g. by packaging.			✓ ¹	
	If materials sensitive to humidity are used in the device, they shall be protected against the effects of humidity e.g. by suitable packaging.	✓ ¹			
Art 6.5	Mass				
	The mass of the ready-for-use device without packaging or carrying device shall not exceed 1000 g.	✓ ¹			
Art 6.6	Conditioning				
	Prior to laboratory or practical performance tests all test specimen shall be conditioned.	✓ ¹			
Art 6.7	Connections				
	Connections between components shall be designed such that they cannot be readily separated by the user.	✓ ¹			
	The connection between filter and hood assembly shall withstand axially a tensile force of 50 N.			✓ ¹	
Art 6.8	Packaging				
	The packaging shall be easy to open without tools.	✓ ¹			

Article of the standard EN 403	Content	Conformity*			Comments
		Yes	No	N-A	
Art 6.12	Valves The complete device may be provided with one or more inhalation and exhalation valves. If the device is equipped with valves, the valves shall operate correctly and independent of their orientation. They shall be protected against dirt and mechanical damage.	✓ ¹			
Art 6.13	Breathing resistance The inhalation resistance shall not exceed 8 mbar and the exhalation resistance shall not exceed 3 mbar.	✓ ¹			
Art 6.14	Flammability The materials used shall not present a danger for the wearer and shall not be of highly flammable nature. The filtering smoke hood or other exposed parts shall not continue to burn or present any additional hazard to the wearer. It is not required that the filtering smoke hood still has to be useable after the test.	✓ ¹ ✓ ¹			
Art 6.15	Carbon dioxide content of inhalation air The carbon dioxide content of inhalation air (dead space) shall not exceed an average of 2 % by volume.	✓ ¹			
Art 6.17	Vision				
Art 6.17.1	Visor The visors shall be reliably assembled to the device.	✓ ¹			
Art 6.17.2	Impairment of vision Visors shall not distort vision as determined in practical performance tests. There shall be no significant impairment of vision by fogging as determined in practical performance tests.	✓ ¹			
Art 6.17.3	Field of vision The field of vision is acceptable if determined so in practical performance tests.	✓ ¹			
Art 6.18	Sealing Each complete device or filter component shall be sealed and shall not be resealable except by the use of special equipment. The sealing shall be such that it can readily be opened when necessary but not inadvertently. When the packaging seal has been broken this shall be obvious by visual inspection.	✓ ¹			
Art 6.20	Ingress of humidity If materials sensitive to humidity are used these materials shall be protected against humidity. After conditioning in accordance with 7.4 the device shall meet the requirements of this standard.	✓ ¹			
Art 6.22	Communication A person wearing the device shall be able to hear verbal communications from the test supervisor. A person wearing the device shall be able to communicate verbally. This does not apply when the device is equipped with a mouthpiece assembly.	✓ ¹ ✓ ¹			

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

¹ The evaluation results are details in the original CE type examination file as defined in paragraph 9.1

9.3. Gas capacity tests

A very short gas capacity is declared for this PPE. Gas capacity tests were carried out. Results of the tests cannot be used to declare any level of gas protection.

No standard	Special requirements	Conformity*			Comments
		Yes	No	N-A	
	<p>For each gas, three filters were tested after conditioning according to 6.6 of EN 403</p> <p>Gas capacity tests were carried out according to EN 14387+A1:2008 with specific deviation defined in table below.</p> <p>Minimum breakthrough time at test condition: 15min</p>	✓ ¹			

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

¹ The evaluation results are details in the original CE type examination file as defined in paragraph 9.1

9.4. Particles exposure tests

No standard	Special requirements	Conformity*			Comments
		Yes	No	N-A	
	<p>For each gas, three filters were tested after conditioning according to 6.6 of EN 403</p> <p>Particles exposure tests were carried out according to EN 13274-7:2008 at 15l/min and 60mg exposure.</p> <p>Maximum penetration during the exposure : 6%</p>	✓ ¹			

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

¹ The evaluation results are details in the original CE type examination file as defined in paragraph 9.1

10. Conclusion

The PPE category III – Particles filtering device with hood for escape Identified in paragraph 4 meet 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 reference specification (defined in §5) and with the conformity of manufacturer's technical documentation.

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

Trade Mark: DURAM MASK

Model: 4NE1

Number of UE Type examination certificate: 0082/2456/079/01/18/0059