



SAFETY PROTECTION

BRETHABLE AND COMFORTABLE

A&Z CLEARS FEP2 NR. A&Z CLEARS 2001 + AT 2

TECHNICAL DATASHEET A&ZMED Mask FFP2

SCOPE

The technical file covers the quality and factory manufacturing control requirements used during the manufacture of Respiratory Protective Devices - Filtering Half Masks for Protection Against Particles, compliance with the essential health and safety requirements associated with the European Union Directive 2016/425/EU Provisions.

"İbişler Tekstil San. Ve Dış Tic. A.Ş. " Technical File;

EN 149: 2001 + A1: 2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking It has been prepared for the evaluation of the conformity of the standard. Referenced standart sor documents:

INSTRUCTIONS FOR USE

1. Shape the mask into a dome shape with the nose clip on top and take it in your palm.

2. Mask; It is worn by holding the tires so that the strip on the upper side is on the bridge of the nose.

3. The rubber is placed on the auricle.

4. Adjust the nose clip by using both hands, tightening it according to your nose shape. Adjusting by compression with one hand can reduce the effect of the mask.

5. To understand the fit and tightness of the mask, take a deep breath and check that no air is entering around the nose. For this, readjust the nose clip if necessary. Then enter the area of work you work in.

IMPORTANT!

It is very important that users are trained in the correct use of the product. If there is difficulty in breathing or the mask is damaged or deformed, or if the face is not suitable, the mask should be changed immediately. Carefully following the instructions is an important step in safe mask use.

PRE-USE CHECKS:

1. Please read the instruction carefully before using.

2. Check the expiry date of the product.

3. Check the fit of the mask to the area used by looking at the markings on the mask.

- 4. Check the mask headbands.
- 5. Check the mask nose clip.
- 6. Check if the mask is damaged

CONFORMITY CHECK

With both hands, grasp the product from the front so as not to affect the fit of the mask on the face.

a) VALVE-FREE Masks, Breathe Strongly

b) VALVE Masks, Breathe Strongly

If there is leakage around the nose, readjust the nose clips to eliminate the leak. Then repeat the above steps. If there is leakage from the mask edges, make sure the head straps are fitted correctly to eliminate the leak. Then repeat the above process. If the necessary compliance cannot be achieved despite all procedures, do not enter the danger zone. Consult your supervisors.

STORAGE

- It should be kept in its original packaging.
- The temperature of the storage area should be between 20 ° C / + 40 °C.
- Ambient Humidity should not be more than 80%.
- Half masks should be protected against the effects of aggressive chemicals, moisture and dirt.
- Half masks are disposable and maintenance free.
- If the above conditions are met, the shelf life is 2 years.

SECURITY PRECAUTIONS

• Failure to follow instructions and restrictions on the use of this product may reduce the effectiveness of the mask and cause illness or death.

• A properly selected mask should be used for your respiratory safety. Before using your product, it is recommended to consult a Workplace Physician or Occupational Safety Specialist about the suitability of the product for your intended use.

• Your product does not provide oxygen. Use only in environments with sufficient oxygen. Do not use this product when the oxygen concentration is less than 19.5%.

- Do not use this product in places containing hazardous contents.
- Do not use this product in explosive atmospheres.
- a) if breathing becomes difficult (b) if dizziness or other discomfort occurs, leave the work area immediately and go to fresh air.
- It is important that the mask fits your face well for full performance. Beard can prevent this. Wear the mask without a beard.
- Never alter or modify the mask.
- The NR marked masks are for single use only. It does not require maintenance. Please do not reuse the mask after a single use.
- Keep the masks away from direct sunlight until the moment of use.











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EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1306

Respiratory protective devices, filtering half masks to protect against particles manufactured by

İbişler Tekstil Sanayi ve Dış Tic. A.Ş.

Orhan Gazi Mah Tunç Cad. B No:5 B Esenyurt İstanbul TURKEY are tested and evaluated according to

EN 149:2001 + A1:2009 Respiratory Protective Devices -Filtering Half Masks to Protect Against Particles -Regirements, Testing, Marking

Based on the type (amination (aducted ith e eva ation) fest reports, technical file according to Persona Protective E upment equation (20) 20, 425 Annex 5, it is approve that he product eets the equation is approved in the equation. U) 20، 425 Annex 5, it is approved

Product Demnition

Brand Name: A&Z MED Model: OLI 2025

Filtering half mask Classification: FFP2 NR

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|---------|-----|--------------------|-----------|---------|-------------|---|--|------------|---------|---|
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| | Eq | 'pmen [†] | egulat | n (EU) | 016/425 / | nex 9. | | | | |
| 2010.00 | 0 | | C 1 | C | C*1 | AND A DESCRIPTION OF A | 1. | | | |

Protective Equipment Regulation (EU) 2016/425 and harmonised standards, ensured by assessments based on Annex 7 (Module C2) or Annex 8 (Module D) of the regulation no later than 1 year from the beginning of serial production

This certificate is initially issued on 18/08/2020 and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.



Suat KA UNIVERSAL CERTIFICATION

Director

Verify the validity with the QR code



This is to Certify that



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ASZ A&ZMED

ORHANGAZİ MAH. TUNÇ CAD. NO:5/B ESENYURT / İSTANBUL, TURKEY

Conforms to the Requirements of

ISO 9001:2015

Quality Management System

Tulum ve Medikal Maske Dikimi ve Satışı.

Jumpsuit and Medical Mask Sewing and Sale.

Certificate Number Certification Period : Q.020.080.TR : 3 Years / 16.04.2023

Expiry Date : 17.04.2023 Certified Date : 17.04.2020

Approving Officer:





HMI Certification Training Ltd. 492 Bearwood Rd, Smethwick B66 4HB, Birmingham / West Midland - England This certificate remains the property of HMI it is valitidy is subject to arrangement between the certificated client and HMI. For further details go to WWW.bvcscert.com This is to Certify that



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Conforms to the Requirements of

ISO 13485:2016

Medical Device Quality Management System

Tulum, Medikal Önlük ve Medikal Maske Dikimi ve Satışı.

Jumpsuit, Medical Gowns and Medical Mask Sewing and Sale .

Certificate Number Certification Period : M.020.080.TR : 3 Years / 16.04.2023 Expiry Date : 17.04.2023 Certified Date : 17.04.2020

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| Article 7.17 | Clogging: This test is not applied to Particle Filtering Half Mask which is not reusable. (<i>For single shift use devices, the clogging test is optional test. For re-usable devices test is mandatory.</i>) |
|------------------------|--|
| <i>Article</i> 7.18 | Demountable Parts: There are no demountable parts on the product. |
| Article 8 | Testing: All tests conducted according to Clause 8 of this standard is available in the test report and are evaluated in this report for qualification and classification of the mask. |
| - | Marking – Packaging: Necessary markings are available on the product package (box). The manufacturer and its trademark is clearly visible. The type of the mask and the classification including the status of re-usability, the reference to EN 149:2001+A1:2009 standard, the end date of shelf life, using and storage instructions and pictograms and CE mark are available on the product package. The above evaluation is based on the technical document for packaging and marking, for box design. Verified on the technical file. |
| Article 9 | The technical documentation for mask design (drawing) also evaluated for marking requirements, drawing OLI 2025. The mask template (drawing) indicates that the mask will carry information about the manufacturer type of mask, the reference to EN 149+A1:2009 standard and classification including the re-usability of the mask. The manufacturer also printed CE mark with our Notified Body number. The mask do not have sub-assemblies. The marking statement given in the technical documentation was not available on the tested specimen, the manufacturer shall consider to use the marking as stated in the technical file in case of serial manufacturing. Model OLI 2025 drawing exists in the technical file of the manufacturer. |
| Article 10 | Information to be supplied by the manufacturer: In each of the smallest commercially available packaging of the product, implementation (installation instructions) pre-use controls, warning and usage limitations, storage and meanings of symbols / pictograms are defined. User instruction document in the technical file found to be appropriate. The manufacturer shall include this documented user information text in every smallest commercially available package. |

| PREPARED BY | APPROVED BY |
|---------------------------|--------------------------------|
| Osman CAMCI PPE Expert | Suat KAÇMAZ General Manager |
| | Potified Boos |

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UNIVERSAL CERTIFICATION and SURVEILLANCE SERVICES TRADE CO. Necip Fazil Bulvari Keyap Sitesi E2 Blok No:44/84 Yukari Dudullu Umraniye, Istanbul / TURKEY

TEST REPORT

Report Date: 17.08.2020 **Report Number**: 08-2020-T-0309

CLIENT and SAMPLE INFORMATION

| | | <u>.</u> | | | | | |
|---|--|---|--|----------------------|------------|--|--|
| TEST OWNER | İBİŞLER TEKSTİL SANAYİ VE DIŞ TİC. A.Ş. | | | | | | |
| ADDRESS | ORHAN GAZ | ORHAN GAZİ MAH TUNÇ CAD. B NO:5 B ESENYURT İSTANBUL | | | | | |
| SAMPLE DESCRIPTION | Folding type p | Folding type protective mask | | | | | |
| BRAND NAME – MODEL | A&Z MED / C | DLI 2025 | | | | | |
| TESTING STANDARD | EN 149+A1:20 | 009 | | | ÷ | | |
| CASE NUMBER | CE-PPE-3315 | | | | | | |
| SAMPLE RECEIVE DATE | 20.07.2020 TESTING START DATE 20.07.2020 | | | | 20.07.2020 | | |
| DISINFECTION INSTRUCTION If applicable | Not given, single use only | | | | | | |
| NUMBER OF SAMPLES | 50 | SAMPLE I | IDs: 1 – 46 | | | | |
| AS RECEIVED SAMPLE NO | 26-46 | L | | | | | |
| | Simulated wearing treatment | | 1-2-3-4-5-6-7-8-9 (As Received) | | | | |
| CONDITIONING SAMPLE NO | Temperature conditioning | | 10-11-12-13-14-15 (Sample after test of Mechanical Strength) | | | | |
| | | | 16-17-18-19-20-21-22-23-24-25 (As Received) | | | | |
| | Mechanical str | rength | 10- | 11-12-13-14-15 (As R | Received) | | |

The results given in this test report belongs to the samples tested. The report content cannot be recreated partially without the written consent of UNIVERSAL CERTIFICATION.

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Suat KAÇMAZ Director

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1. REPORT SUMMARY

| TEST STANDARD | TEST NAME | RESULT | EVALUATION | |
|--|---|--------|-------------|--|
| EN 149:2001 + A1:2009 clause 8.5 | Total Inward Leakage Testing | Pass | FFP2 | |
| EN 13274-1:2001 | roun mara Dounago rosning | 1 255 | FFF2 | |
| EN 149:2001 + | | | | |
| A1:2009 clause 8.11 EN 13274-7:2019 | Penetration of Filter Material | Pass | FFP2 | |
| EN 149:2001 + | | | | |
| A1:2009 clause 8.6 | Flammability Testing | Pass | See results | |
| EN 13274-4:2001 | | | | |
| EN 149:2001 + A1:2009 clause 8.7 EN 13274-6:2001 | Carbon Dioxide Content of The Inhalation Air Testing | Pass | See results | |
| EN 149:2001 + | Breathing Inhalation Resistance-30 l/min | Pass | See results | |
| A1:2009 clause 8.9 EN 13274-3:2001 | Breathing Inhalation Resistance-95 l/min | Pass | See results | |
| EN 149:2001 + A1:2009 clause 8.9 EN 13274-3:2001 | Exhalation Resistance, flow rate 160 l/min | Pass | See results | |



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7.4 PACKAGING (EN 149:2001 + A1:2009 clause 8.2)

Test Method: Clause 8.2-Visual inspection

| REQUIREMENT | RESULTS | COMMENT |
|---|---------|--|
| 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. | Pass | The masks were packaged in sealed plastic bags, in larger plastic bags inside a large cardboard box that gave some protection against mechanical damage or contamination before use |

Lab A

2.

7.5 MATERIAL (EN 149:2001 + A1:2009 clause 8.2, 8.3.1, 8.3.2)

Test Method: Clause 8.2-Visual inspection

Clause 8.3.1-Simulated wearing treatment

A breathing machine is adjusted to 25 cycles/min and 2,0 l/stroke. The particle filtering half mask was mounted on a Sheffield dummy head.

For testing, a saturator is incorporated in the exhalation line between the breathing machine and the dummy head, the saturator being set at a temperature in excess of 37 °C to allow for the cooling of the air before it reaches the mouth of the dummy head.

The air has been saturated at (37 ± 2) °C at the mouth of the dummy head

Clause 8.3.2-Temperature conditioning

The ambient temperature for testing has been between 16 °C and 32 °C and the temperature limits has been subject to an accuracy of ± 1 °C.

a) for 24 h to a dry atmosphere of (70 ± 3) °C;

b) for 24 h to a temperature of (-30 ± 3) °C; and allow to return to room temperature for at least 4 h between exposures and prior to subsequent testing. The conditioning has been carried out in a manner which ensures that no thermal shock occurs.

| REQUIREMENT | RESULTS | <u>COMMENT</u> |
|---|----------------|---|
| 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. | Pass | The materials used were able to withstand handling and wear during the limited laboratory testing carried out. |
| Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer. | Pass | It was not constitute a hazard or nuisance for the wearer. |
| After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps. | Pass | None of the specimens conditioned suffered mechanical failure. |
| When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse. | Pass | None of the specimens had not collapse after conditioning. |

Lab B



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7.6 CLEANING AND DISINFECTING (EN 14922001 HFAII62009 člauše 8.4, 8.5, 8.11)

Test Method: Described in Clause 8.4, 8.5 and 8.11

| REQUIREMENT | RESULTS | COMMENT |
|--|---------|--|
| 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. With reference to 7.9.2, after cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class. | N/A | This article is not applicable for tested protective mask which is single use disposable mask. |

7.7 PRACTICAL PERFORMANCE (EN 149:2001 + A1:2009 clause 8.4)

Test Method: Described in Clause 8.4

| | • | 1 |
|---|------------------|-------------------------|
| REQUIREMENT | RESULTS | COMMENT |
| 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. | No imperfections | Detail refer to Annex I |
| Two as received mask samples are used by two subject for the walking (10 mins walking with a speed of 6km/h) and work simulation (bended walking, crawling and basket filling exercises) tests. | ~ | |

Annex I-Test Result:

Number of sample: 29 (A.R), 30 (A.R)

| Assessed elements | Positive Assessment | Negative Assessment | Requirements in accordance with EN 149:2001+A1:2009 | Assessment of Test Result Conformity / Nonconformity |
|---|------------------------|------------------------|---|---|
| The face piece fitting Head harness comfort Security of fastenings Field of vision | 2 2 2 2 | 0 0 0 0 | Filtering half masks should not have imperfections related to wearer's acceptance | Filtering half masks fulfil requirements of the standard EN 149:2001 + A1:2009 given in 7.7 No imperfections |

The subjects (MEG and MA) were able to complete the exercises and did not report any nuisance or problem with the mask. Lab B

7.8 FINISH OF PARTS (EN 149:2001 + A1:2009 clause 8.2)

Test Method: Described in Clause 8.2

| REQUIREMENT | RESULTS | COMMENT |
|--|---------|---|
| Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs. | Pass | None of the specimens used in laboratory testing showed evidence of sharp edges or burrs while visual inspection and performance tests. |

Lab A





7.9.1 TOTAL INWARD LEAKAGE (EN 149:200 R市在1:2009公園 use 影5)

Test Method: Described in Clause 8.5

| REQUIREMENT | RESULTS | COMMENT |
|--|---------|---|
| The total inward leakage consists of three components: face seal leakage, exhalation value leakage (if exhalation value 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 results shall be not greater than: 25 % for FFP1, 11 % for FFP2, 5 % for FFP3 and in addition at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall not be greater than: 22 % for FFP1, 8 % for FFP2, 2 % for FFP3 | Pass | Classified as FFP2 Detail refer to Annex II |

Annex II-Test Result:

The test results obtained are given in the tables as follows

| Test Subject | No of sample | Cond. | 1. Walk (%) | Head side/ side (%) | Head up/down (%) | Talk (%) | 2. Walk (%) | Average (%) |
|-----------------|--------------|-------|--------------------------------------|------------------------|---------------------------------------|----------|-------------|-------------|
| 1 | 31 | A.R. | 5,37 | 5,93 | 5,15 | 6,40 | 6,03 | 5,78 |
| 2 | 32 | A.R. | 4,58 | 4,76 | 5,92 | 5,98 | 4,60 | 5,17 |
| 3 | 33 | A.R. | 6,00 | 6,20 | 4,60 | 4,72 | 4,67 | 5,24 |
| 4 | 34 | A.R. | 4,84 | 5,88 | 6,02 | 5,59 | 5,53 | 5,57 |
| 5 | 35 | A.R. | 4,91 | 6,23 | 5,27 | 6,27 | 5,67 | 5,67 |
| 6 | 16 | T.C. | 4,87 | 4,75 | 5,71 | 5,25 | 6,37 | 5,39 |
| 7 | 17 | T.C. | 6,51 | 5,32 | 4,90 | 6,48 | 5,71 | 5,78 |
| 8 | 18 | T.C. | 5,43 | 6,26 | 5,26 | 6,08 | 5,38 | 5,68 |
| 9 | 19 | T.C. | 6,34 | 5,10 | 6,30 | 5,94 | 6,30 | 5,99 |
| 10 | 20 | T.C. | 6,17 | 5,42 | 5,87 | 5,91 | 6,06 | 5,89 |
| | | | e not greater tha eans were not g | | · · · · · · · · · · · · · · · · · · · | | · | Pass (FFP2) |

| And | marviauai | excretise results were not greater than 11 76 | |
|--------|--------------|---|---|
| All 10 |) individual | wearer arithmetic means were not greater than 8 | % |

| Test Subject | Face Length (mm) | Face Width (mm) | Face Depth (mm) | Mouth Width (mm) |
|-----------------|------------------|-----------------|--------------------|---------------------|
| 1 | 117 | 155 | 130 | 60 |
| 2 | 113 | 148 | 128 | 62 |
| 3 | 112 | 160 | 134 | 59 |
| 4 | 115 | 148 | 125 | 61 |
| 5 | 120 | 158 | 132 | 57 |
| 6 | 118 | 150 | 134 | 59 |
| 7 | 115 | 152 | 130 | 57 |
| 8 | 117 | 155 | 134 | 59 |
| 9 | 114 | 149 | 128 | 57 |
| 10 | 110 | 150 | 131 | 55 |

For Information Only

Lab B



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7.9.2 PENETRATION OF FILTER MATERIAE (EN11#9:2001T+1A1 22009 clause 8.11)

Test Method: Described in Clause 8.11

| REQUIREMENT | | | RESULTS | COMMENT | |
|--|---|--|---------|-------------------------------------|--|
| Classification FFP1 FFP2 FFP3 | Max penetratio NaCl test 95 l/min %max 20 6 1 | n of test aerosol Paraffin oil test 95 l/min %max 20 6 1 | Pass | Detail refer to Annex IIIA and IIIB | |

Annex IIIA-Test Result:

The test results obtained are given in the tables as follows;

| No. of Sample | Condition | Penetration of Sodium Chloride in accordance with EN 13274- 7:2019 [%] Flow rate 95 l/min | Requirements in accordance with EN 149:2001+A1:2009 | Assessment of Test Result Conformity / Nonconformity |
|------------------|---|---|---|---|
| 36 37 38 | As received | 0,83 0,87 0,66 | FFP1 ≤ 20 % | Passed Filtering half masks |
| 1 2 3 | Simulated wearing treatment | 0,70 1,09 0,72 | $FFP1 \leq 20\%$ FFP2 $\leq 6\%$ | fulfil the requirements of the standard EN 149:2001+A1:2009 |
| 10 11 12 | Mechanical strength + Temperature conditioned | 0,50 0,78 1,09 | FFP3 ≤ 1 % | given in 7.9.2 in range of the first, second protection class (FFP1, FFP2) |

Annex IIIB-Test Result:

The test results obtained are given in the tables as follows:

| No. of Sample | Condition | Penetration of Paraffin Oil Mist in accordance with EN 13274-7:2019 [%] Flow rate 95 J/min | Requirements in accordance with EN 149:2001+A1:2009 | Assessment of Test Result Conformity / Nonconformity |
|------------------|---|--|---|--|
| 39 | | 1,62 | | Passed |
| 40 41 | As received | 1,14 1,96 | FFP1 ≤ 20 % | Filtering half masks fulfil |
| 4 5 6 | Simulated wearing treatment | 1,70 1,65 1,61 | FFP2 ≤ 6 % | the requirements of the standard EN 149:2001+A1:2009 given |
| 13 14 15 | Mechanical strength + Temperature conditioned | 1.66 1.39 1.98 | FFP3 ≤ 1 % | in 7.9.2 in range of the first, second protection classes (FFP1, FFP2) |

Lab A + B

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7.10 COMPATIBILITY WITH SKIN (EN 149:2001 7 IAH 22009 TIAUSe 8.4, 8.5)

Test Method: Described in Clause 8.4 and 8.5.

| REQUIREMENT | RESULTS | COMMENT |
|--|---------|---|
| 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. | Pass | No irritation or any other adverse effect to health or sensitivity reported by the subjects during the practical performance and TIL tests. |

Lab B

7.11 FLAMMABILITY (EN 149:2001 + A1:2009 clause 8.6)

Test Method: Described in Clause 8.6

| REQUIREMENT | RESULTS | COMMENT |
|--|---------|--------------------------|
| 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 5s after removal from the flame. | Pass | Detail refer to Annex IV |

Annex IV-Test Result: The test results obtained are given in the tables as follows:

| No. of Sample | Condition | Visual inspection | Requirements in accordance with EN 149:2001+A1:2009 | Assessment of Test Result Conformity / Nonconformity |
|------------------|-------------|-------------------|--|---|
| 45 | | 0,3 s | Filtering half mask | Passed |
| 46 | As received | 0,3 s | shall not burn or not | Filtering half masks fulfil |
| 21 | Temperature | 0,5 s | continue to burn for more than 5 s after | requirements of the standard EN 149:2001 + |
| 22 | conditioned | 0,4 s | removal from the flame | A1:2009 given in 7.11 |

Lab B

7.12 CARBON DIOXIDE CONTENT OF THE INHALATION AIR (EN 149:2001 + A1:2009 clause 8.7)

Test Method: Described in Clause 8.7

| REQUIREMENT | RESULTS | COMMENT | _ |
|--|----------------|-------------------------|---|
| The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume) | Pass | Detail refer to Annex V | |

Annex V-Test Result: The test results obtained are given in the tables as follows:

| No. of Sample | Condition | CO ₂ content of the inhalation air [%] by volume | An average CO ₂ content of the inhalation air [%] by volume | Requirements in accordance with EN 149:2001+A1:2009 | Assessment of Test Result Conformity / Nonconformity |
|------------------|-------------|--|---|---|--|
| 26 | | 0,64 | | CO ₂ content of the inhalation air shall | Passed Filtering half masks fulfil |
| 27 | As received | 0,75 | 0,71 | not exceed an | requirements of the |
| 28 | | 0,74 | | average of 1,0% by volume | standard EN 149:2001 + A1:2009 given in 7.12 |

Lab B



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7.13 HEAD HARNESS (EN 149:2001 + A1:2009 clause 8.4, 8.5)

Test Method: Described in Clause 8.4, 8.5

| REQUIREMENT | RESULTS | COMMENT |
|--|---------|--|
| The head harness shall be designed so that the particle filtering half-mask can be donned and removed easily. | Pass | No problem with the head harness reported by the wearers during the practical performance test. |
| 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 capable of maintaining total inward leakage requirements for the device. | Pass | No problem with the head harness reported by the wearers during the practical performance test. |
| Lab B | | |

7.14 FIELD OF VISION (EN 149:2001 + A1:2009 clause 8.4)

Test Method: Described in Clause 8.4

| REQUIREMENT | RESULTS | COMMENT |
|--|---------|---|
| The field of vision is acceptable if determined so in practical performance tests. | Pass | There were no adverse comments following practical performance tests. |

Lab B

7.15 EXHALATION VALVE (EN 149:2001 + A1:2009 clause 8.2, 8.3.4, 8.8, 8.9.1)

Test Method: Clause 8.2, 8.3.4, 8.8, 8.9.1

| REQUIREMENT | RESULTS | COMMENT |
|--|---------|--|
| A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations. | N/A | No exhalation valve in tested samples. |
| 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 | N/A | No exhalation valve in tested samples. |
| Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30s. | N/A | No exhalation valve in tested samples. |
| When the exhalation valve housing is attached to the face blank, it shall withstand axially a tensile force of 10N applied for 10s. | N/A | No exhalation valve in tested samples. |

Lab -

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7.17 CLOGGING (EN 149:2001 + A1:2009 clause 8.9, 8H0)C ATION

Test Method: Described in Clause 8.8, 8.10

| REQUIREMENT | RESULTS | COMMENT |
|--|---------|--|
| Valved particle filtering half masks: After clogging the inhalation resistances shall not exceed: FFP1:4mbar, FFP2:5mbar, FFP3:7mbar at 95L/min continuous flow. The exhalation resistance shall not exceed 3mbar at 160L/min continuous flow. Valveless particle filtering half masks: After clogging the inhalation resistances shall not exceed: FFP1:3mbar, FFP2:4mbar, FFP3:5mbar at | NAs | This is optional test and not desired by client. |
| 95L/min continuous flow | 2.4 | |

Lab -

7.18 DEMOUNTABLE PARTS (EN 149:2001 + A1:2009 clause 8.2)

Test Method: Described in Clause 8.2

| REQUIREMENT | RESULTS | COMMENT | |
|---|----------------|----------------------|--|
| All demountable parts (if fitted) shall be readily connected and secured, where possible by hand | N/A | No demountable part. | |
| Lab - | | | |

| Pass | Requirement satisfied. |
|------|--|
| NCR | Requirement not satisfied. Refer to the "Result details" section for more information. |
| NAs | Assessment not carried out. |
| N/A | Requirement not applicable. |

LABORATORY INFORMATION

| Lab B BELGELENDIRME, GOZETIM, EGITIM Agency with number AB-1252-T according to EN IS VE DIS TICARET LIMITED SIRKETI Agency with number AB-1252-T according to EN IS KOCAELI DILOVA SUBESI 17025:2017. The laboratories are contracted bodies with UNIVERSAL CERTIFICATION and the technical compositions of the laboratories is also under supervision / assessment of UNIVERSAL CERTIFICATION based of provisions of EN ISO/IEC 17065 Requirements for bodies certifying products, processes and service | Code | Laboratory Name | Competency Explanations |
|---|-------|--|---|
| Lab B BELGELENDIRME, GOZETIM, EGITIM Laboratory holds an accreditation by Turkish Acc | Lab A | | Internal Laboratory Services of Notified Body |
| of the laboratories is also under supervision / assessment of UNIVERSAL CERTIFICATION based of provisions of EN ISO/IEC 17065 Requirements for bodies certifying products, processes and service | Lab B | BELGELENDIRME, GOZETIM, EGITIM VE DIS TICARET LIMITED SIRKETI | Laboratory holds an accreditation by Turkish Accreditation Agency with number AB-1252-T according to EN ISO/IEC 17025:2017. |
| standard. Each test result given in this test report shown with the issuing laboratory code. | • | of the laboratories is also under supervision / a provisions of EN ISO/IEC 17065 Requirement standard. | assessment of UNIVERSAL CERTIFICATION based on the ts for bodies certifying products, processes and services |

Each test result given in this test report shown with the issuing laboratory •



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- End of Report -



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