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RETHABLE AND COMFORTABLE



SAFETY PROTECTION



### 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

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nose shape. Adjusting by compression with one hand can reduce the effect

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 chemi-

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.





























⑨ Orhangazi Mah. Tunç Cad. No:5 34538 Esenyurt / İstanbul - TURKEY Deauty.sk:63H**RAvSK4beauty.sk:5HMAvSK4beauty.sk: HPAvSK4beauty.sk** HPA°SK





### 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 -Requirements, Testing, Marking

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation.

**Product Definition** 

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Filtering half mask Classification: FFP2 NR

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.
- Ongoing successful performance in fulfilment of the requirements set out in Personal 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.

2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code



### EU DECLARATION OF CONFORMITY

#### MANUFACTURER

İbişler Tekstil Sanayi ve Dış Tic. A.Ş.

Orhan Gazi Mah Tunç Cad. B No:5 B Esenyurt İstanbul TURKEY

#### PRODUCT DESCRIPTION

Brand Name: A&Z MED Model: OLI 2025 Filtering half mask Classification: FFP2 NR

Particle Filtering Half Face Mask in Category III product accrding to (EU) 2016/425 Personal Protective Equipment Regulation

The Manufacturer declares on his sole responsibility that the product above is, under conditions of normal use and conditions defined by the Manufacturer, safe and meets all the necessary legal conditions and requirements. The product is a personal protective equipment that is intended for single use and solely in accordance with the Manufacturer's instructions.

#### The Conformity is ensured with the following mechanism:

- Complies with EU 2016/425 Personel Protective Equipment Regulation establishing technical requirements for Category III products,
- Complies with Essential Health and Safety Requirements of Technical harmonised standard EN 149:2001 +A1:2009
- All required tests referred in above standards are conducted,
- Complies with other relevant harmonized legislation and community standards

www.4beautythe ksestuplotokorgily the Full types kaming package (Serial Not2163-PPE-HOA'S SK S. 1 issued, after all technical evaluations for conformity to the regulation and harmonised standards conducted, by:

- o UNIVERSAL CERTIFICATION, SURVEILLANCE SERVICES and TRADE Co, as Notified Body number 2163
- The product is under surveillance of same Notified Body, NB 2163 according to the Annex III (Module C2) of the PPE Regulation (EU) 2016/425, for quality assurance.

#### MARKING, LABELLING

Marking, labelling and user information are prepared in accordance with EU 2016/425 Personal Protective Equipment Regulation and the harmonised product standards given above.

#### MEASURES TO ENSURE CONFORMITY

The Manufacturer declares that he has taken all necessary measures to ensure the conformity of products placed on the market with technical documentation and technical requirements for this type of product.

General Manager 19/08/2020 2163

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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**

| TEST OWNER         | İBİŞLER TEKSTİL SANAYİ VE DIŞ TİC. A.Ş.             |
|--------------------|---|
| ADDRESS            | ORHAN GAZİ MAH TUNÇ CAD. B NO:5 B ESENYURT İSTANBUL |
| SAMPLE DESCRIPTION | Folding type protective mask                        |
| BRAND NAME - MODEL | A&Z MED / OLI 2025                                  |
| TESTING STANDARD   | EN 149+A1:2009                                      |
|                    | OF THE COLO   |

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| SAMPLE RECEIVE DATE                     | 20.07.2020                  | 110                | SIII   | O START DATE                    | 20.07.2020 |  |
|---|-----------------------------|--------------------|--|---------------------------------|------------|--|
| DISINFECTION INSTRUCTION  If applicable | Not given, sing             | le use only        |  |                                 |            |  |
| NUMBER OF SAMPLES                       | 50                          | SAMPLE IDs: 1 – 46 |  | 1 – 46                          |            |  |
| AS RECEIVED SAMPLE NO                   | 26-46                       |                    |  |                                 |            |  |
| CONDITIONING SAMPLE NO                  | Simulated wearing treatment |                    |  | 1-2-3-4-5-6-7-8-9 (As Received) |            |  |
|   | 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 strength         |                    | 10-11-12-13-14-15 (As 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.

> Suat KAÇMAZ Director

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#### 1. REPORT SUMMARY

| TEST<br>STANDARD  | TEST NAME   | RESULT | EVALUATION  |
|---|---|--------|-------------|
| EN 149:2001 +<br>A1:2009 clause 8.5<br>EN 13274-1:2001  | Total Inward Leakage Testing                            | Pass   | FFP2        |
| EN 149:2001 +<br>A1:2009 clause 8.11<br>EN 13274-7:2019 | Penetration of Filter Material                          | Pass   | FFP2        |
| EN 149:2001 +<br>A1:2009 clause 8.6<br>EN 13274-4:2001  | Flammability Testing                                    | Pass   | See results |
| EN 149:2001 +<br>A1:2009 clause 8.7<br>EN 13274-6:2001  | Carbon Dioxide Content of The Inhalation<br>Air Testing | Pass   | See results |
| EN 149:2001 +   | Breathing Inhalation Resistance-30 l/min                | Pass   | See results |
| A1:2009 clause 8.9<br>EN 13274-3:2001                   | Breathing Inhalation Resistance-95 l/min                | Pass   | See results |
| EN 149:2001 +<br>A1:2009 clause 8.9                     | 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

#### 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  $(37 \pm 2)$  °C at the mouth of the dummy head

Clause 8.3.2-Temperature conditioning

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a) for 24 h to a dry atmosphere of  $(70 \pm 3)$  °C;

b) for 24 h to a temperature of  $(-30 \pm 3)$  °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 | COMMENT  |
|---|---------|--|
| 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 HFA11C2009 clause 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

| 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.  | 1                |                         |

Annex I-Test Result:

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| Assessed elements  | Positive<br>Assessment | Negative<br>Assessment | Requirements in accordance with EN 149:2001+A1:2009   | Assessment of Test<br>Result<br>Conformity /<br>Nonconformity   |
|--|------------------------|------------------------|---|---|
| The face piece fitting Head harness comfort Security of fastenings Field of vision | 2<br>2<br>2<br>2<br>2  | 0<br>0<br>0<br>0       | Filtering half masks<br>should not have<br>imperfections related<br>to wearer's<br>acceptance | Filtering half masks<br>fulfil requirements of<br>the standard EN<br>149:2001 + A1:2009<br>given in 7.7<br>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<br>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

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#### 7.9.1 TOTAL INWARD LEAKAGE (EN 149:200 R-FTA 1:2009/clause 8:5)

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<br>Subject | No of sample | Cond. | 1. Walk (%) | Head side/<br>side (%) | Head<br>up/down<br>(%) | 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        |

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| Test<br>Subject | Face Length (mm) | Face Width (mm) | Face Depth<br>(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#9:20017+1AI :2009 clause 8.11)

Test Method: Described in Clause 8.11

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

#### Annex IIIA-Test Result:

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

| No. of<br>Sample | Condition  | Penetration of Sodium Chloride<br>in accordance with EN 13274-<br>7:2019<br>[%]<br>Flow rate 95 l/min | Requirements in accordance with EN 149:2001+A1:2009 | Assessment of Test<br>Result<br>Conformity /<br>Nonconformity |
|------------------|--|---|---|---|
| 36               |  | 0.83  |   | Passed  |
| 37<br>38         | As received  | 0,87  | FFP1 ≤ 20 %   | Filtering half masks  |
| 1                | Simulated wearing  | 0.70  | FFF1 \( \sum_{20} \)%                               | fulfil the requirements of                                    |
| 2                | treatment  | 1.09  | FFP2 ≤ 6 %  | the standard EN<br>149:2001+A1:2009                           |
| 3                | The second secon | 0,72  |   | given in 7.9.2 in range of                                    |
| 10               | Mechanical strength  | 0.50  | FFP3 < 1 %  | great in the state of   |

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#### Annex IIIB-Test Result:

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

| No. of<br>Sample | Condition  | Penetration of Paraffin Oil Mist in accordance with EN 13274-7:2019 [%] Flow rate 95 l/min | Requirements in<br>accordance with EN<br>149:2001+A1:2009 | Assessment of Test Result<br>Conformity /<br>Nonconformity |
|------------------|--|--|---|--|
| 39               |  | 1,62   |   | Passed   |
| 40               | As received  | 1,14   |   |  |
| 41               | Common Control of Cont | 1,96   | FFP1 ≤ 20 %   | Filtering half masks fulfil                                |
| 4                | Ci- latel associate  | 1,70   | 30.00002 (== 1.020 ) See                                  | the requirements of the                                    |
| 5                | Simulated wearing  | 1,65   | FFP2 ≤ 6 %  | standard EN  |
| 6                | treatment  | 1,61   |   | 149:2001+A1:2009 given                                     |
| 13               | Mechanical strength +  | 1,66   | FFP3 ≤ 1 %  | in 7.9.2 in range of the first,                            |
| 14               | Temperature  | 1,39   |   | second protection classes                                  |
| 15               | conditioned  | 1,98   |   | (FFP1, FFP2)   |

Lab A + B

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#### 7.10 COMPATIBILITY WITH SKIN (EN 149:2001 FIAF 2009 Tlause8.4, 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<br>sensitivity reported by the subjects during the practical<br>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<br>Sample | Condition   | Visual inspection | Requirements in accordance with EN 149:2001+A1:2009 | Assessment of Test Result<br>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                             |
|                  |             | 0.5               | continue to burn for                                | requirements of the standard EN                         |

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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<br>Sample | Condition   | CO <sub>2</sub> content of<br>the inhalation<br>air [%] by<br>volume | An average CO <sub>2</sub><br>content of the<br>inhalation air [%]<br>by volume | Requirements in accordance with EN 149:2001+A1:2009 | Assessment of Test Result<br>Conformity /<br>Nonconformity |
|------------------|-------------|--|---|---|--|
| 26               |             | 0,64   |   | CO <sub>2</sub> content of the inhalation air shall | Passed<br>Filtering half masks fulfil                      |
| 27               | As received | 0,75   | 0,71  | not exceed an                                       | requirements of the<br>standard EN 149:2001 +              |
| 28               |             | 0,74   |   | average of 1,0% by volume                           | 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<br>particle filtering half-mask can be donned and<br>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<br>and shall be sufficiently robust to hold the particle<br>filtering half mask firmly in position and capable of<br>maintaining total inward leakage requirements for<br>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

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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<br>exhalation valve(s), which shall function correctly in<br>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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7.16 BREATHING RESISTANCE (EN 149:2001 & X 1:2009 clause 8.9)

Test Method: Described in Clause 8.9

|  | REQU     | IREMENT          |            | RESULTS | COMMENT  |
|--|----------|------------------|------------|---------|--|
| Classification   | Max per  | mitted resistanc | e (mbar)   |         | Classified as FFP2   |
| A Committee of the Comm | Inhal    | lation           | Exhalation |         |  |
|  | 30 l/min | 95 l/min         | 160 l/min  | Pass    | Detail refer to Annex VIA-VIB  |
| FFP1   | 0.6      | 2.1              | 3.0        |         | Control of the Contro |
| FFP2   | 0.7      | 2.4              | 3.0        |         |  |
| FFP3   | 1.0      | 3.0              | 3.0        |         |  |

#### Annex VIA-Test Result:

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

Inhalation Resistance

| No. of | Condition   | Inhalation Resistance (mbar)    |   |                                 |   |   |
|--------|-------------|---------------------------------|---|---------------------------------|---|---|
| Sample |             | Flow rate<br>30 l/min<br>[mbar] | Requirements in accordance with EN 149:2001+A1:2009 | Flow rate<br>95 l/min<br>[mbar] | Requirements in accordance with EN 149:2001+A1:2009 | Assessment of<br>Test Result<br>Conformity /<br>Nonconformity |
| 42     |             | 0,51                            |   | 1,89                            |   |   |
| 43     | As received | 0,42                            |   | 1,92                            |   |   |
| 44     |             | 0,44                            | FFP1 < 0.60   | 1,93                            | FFP1 ≤ 2,10   |   |
| 7      | Simulated   | 0,41                            | Section 1997  | 1,89                            | 102me2 = 72M  | Passed<br>Oualifies   |
| 8      | wearing     | 0,57                            | FFP2 ≤ 0,70   | 1,92                            | FFP2 ≤ 2,40   | FFP1 FFP2,  |

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|---|-------|-----------------|---------|------------|-------------------|-------------|-----------|-------|
| ľ | 23    | T               | 0,50    | FFP3 ≤ 1.0 | 1,98              | FFP3 ≤ 3,00 |           |       |
|   | 24    | Temperature     | 0,54    |            | 1,94              |             |           |       |
| ı | 25    | conditioned     | 0.44    |            | 1.95              |             |           |       |

**Exhalation Resistance** 

| No. of<br>Sample | Condition               | Flow<br>rate | Facing directly | Facing<br>vertically<br>upwards | Facing<br>vertically<br>downwards | Lying on the left side | Lying on the right side | Requirements in<br>accordance with<br>EN<br>149:2001+A1:2009 | Assessment of<br>Test Result<br>Conformity /<br>Nonconformity |
|------------------|-------------------------|--------------|-----------------|---------------------------------|-----------------------------------|------------------------|-------------------------|--|---|
| 42               |                         |              | 2,09            | 2,24                            | 2,13                              | 1,99                   | 2,25                    |  |   |
| 43               | As received             |              | 2,07            | 2,14                            | 2,26                              | 2,03                   | 1,91                    |  |   |
| 44               |                         |              | 2,16            | 2,25                            | 2,01                              | 2,05                   | 2,25                    | FFP1 ≤ 3,0   | Passed  |
| 7                | Simulated               | 1            | 2,23            | 2,00                            | 1,97                              | 2,29                   | 2,15                    | **** - ***   | Qualifies   |
| 8                | wearing                 | 1601/min     | 2,07            | 1,92                            | 1,93                              | 2,18                   | 2,04                    | FFP2 ≤ 3,0   | FFP1, FFP2,   |
| 9                | treatment               |              | 1,91            | 2,27                            | 2,22                              | 2,28                   | 1,90                    |  | FFP3  |
| 23               | m                       |              | 2,24            | 2,07                            | 2,26                              | 2,26                   | 2,16                    | FFP3 ≤ 3,0   |   |
| 24               | Temperature conditioned |              | 2,26            | 2,00                            | 1,96                              | 1,94                   | 2,04                    |  |   |
| 25               |                         |              | 1,92            | 2,29                            | 1,98                              | 1,91                   | 2,01                    |  |   |

Lab A

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7.17 CLOGGING (EN 149:2001 + A1:2009 clause 8.9, 8 HO)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 95L/min continuous flow | NAs     | This is optional test and not desired by client. |

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. |

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| 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

| Code  | Laboratory Name  | Competency Explanations  |  |  |  |
|-------|--|--|--|--|--|
| Lab A | UNIVERSAL SERTIFIKASYON VE<br>GOZETIM HIZMETLERI TIC. LTD. STI.  | Internal Laboratory Services of Notified Body  |  |  |  |
| Lab B | GCNTR ULUSLARARASI BELGELENDIRME, GOZETIM, EGITIM VE DIS TICARET LIMITED SIRKETI KOCAELI DILOVA SUBESI | Laboratory holds an accreditation by Turkish Accreditation Agency with number AB-1252-T according to EN ISO/IEC 17025:2017.  |  |  |  |
| •     | of the laboratories is also under supervision /  | UNIVERSAL CERTIFICATION and the technical competence assessment of UNIVERSAL CERTIFICATION based on the nts for bodies certifying products, processes and services |  |  |  |
| •     | Each test result given in this test report shown with the issuing laboratory code.                     |  |  |  |  |

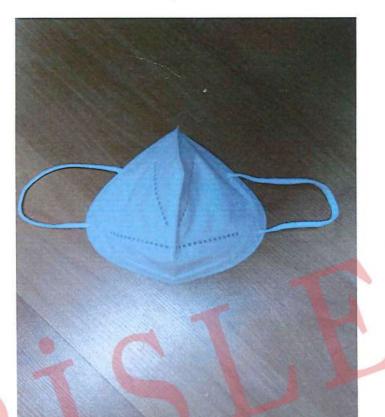
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