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NB 2163

# EU TYPE EXAMINATION CERTIFICATE

**Certificate No: 2163-PPE-1593**

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

**BUDAK TESKTİL SAN. VE TİC. LTD. ŞTİ.**

Adnan Kahveci Mah. Gülyali Cad. No:4 Beylikdüzü 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**

**Model:** P0102
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 **21/10/2020** and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

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# TECHNICAL ASSESSMENT REPORT

**REPORT DATE / NO:** 21.10.2020 / 2163-KKD-1593

**Manufacturer:** BUDAK TESKTİL SAN. VE TİC. LTD. ŞTİ.
**Address:** Adnan Kahveci Mah. Gülyali Cad. No:4 Beylikdüzü İstanbul TURKEY

This report is for the, given above, manufacturer prepared according to the test results obtained from Universal Certification And Surveillance Services Trade Co dated 21.10.2020 with Serial Id 10-2020-T0461 based on EN 149: 2001 + A1: 2009 standard and the technical file dated 09 October, 2020 Version 01 provided by the manufacturer.

The technical file of the manufacturer, and risk evaluation against the essential health safety requirements and the test report evaluated for their relation with Essential Requirements of Personel Protective Equipment Regulation and found to be appropriate.

This report is an annex and an integral part of the EU Type Examination Certificate issued to the manufacturer. The test results and issued certificate belongs only to the tested model. The technical report consists of a total of 6 pages.

**Product Description:** Particle Filtering Half Mask
**Classification:** FFP2 NR
**Model:** P0102


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## ESSENTIAL HEALTH and SAFETY REQUIREMENTS GIVEN IN EUROPEAN UNION REGULATION EU 2016/425 CORRESPONDING RISKS FOR THE PRODUCT

**1.1. Design principles**

**1.1.1. Ergonomics**

PPE must be so designed and manufactured that in the foreseeable conditions of use for which it is intended the user can perform the risk related activity normally whilst enjoying appropriate protection of the highest possible level.

**1.1.2. Levels and classes of protection**

**1.1.2.1. Highest level of protection possible**

The optimum level of protection to be taken into account in the design is that beyond which the constraints by the wearing of the PPE would prevent its effective use during the period of exposure to the risk or normal performance of the activity.

**1.1.2.2. Classes of protection appropriate to different levels of risk**

Where differing foreseeable conditions of use are such that several levels of the same risk can be distinguished, appropriate classes of protection must be taken into account in the design of the PPE.

**1.2. Innocuousness of PPE**

**1.2.1. Absence of risks and other inherent nuisance factors**

PPE must be so designed and manufactured as to preclude risks and other nuisance factors under fore seeable conditions of use.

**1.2.1.1. Suitable constituent materials**

The materials of which the PPE is made, including any of their possible decomposition products, must not adversely affect the health or safety of users.

**1.2.1.2. Satisfactory surface condition of all PPE parts in contact with the user**

Any part of the PPE that is in contact or is liable to come into contact with the user when the PPE is worn must be free of rough surfaces, sharp edges, sharp points and the like which could cause excessive irritation or injuries

**1.2.1.3. Maximum permessible user impediment**

Any inpediment caused by PPE to movements to be made, postures to be adopted and sensory perception must be minimized; nor must PPE cause movements which endanger the user or other persons.

**1.3 Comfort and effectiveness**

**1.3.1. Adaptation of PPE to user morphology**

PPE must be designed and manufactured in such a way as to facilitate its correct positioning on the user and to remain in place for the foreseeable period of use, bearing in mind ambient factors, the actions to be carried out and the postures to be adopted. For this purpose, it must be possible to adapt the PPE to fit the morphology of the user by all appropriate means, such as adequate adjustment and attachment systems or the provision of an adequate range of sizes.

**1.3.2. Lightness and design strength**

PPE must be as light as possible without prejudicing design strength and efficiency.

Apart from the specific additional requirements which they must satisfy in order to provide adequate protection against the risks in question (see 3), PPE must be capable of withstanding the effects of ambient phenomena inherent under the foreseeable conditions of use

**1.4. Information supplied by the manufacturer**

The notes that must be drawn up by the former and supplied when PPE is placed on the market must contain all relevant information on:

a) In addition to the name and addressof the manufacturer and/or his authorized representative established in the Community
b) Storage, use, cleaning, maintenance, servicing and disinfection. cleaning, maintenance or disinfectant protection recommended by manufacturers must have no adverse effect on PPE or users when applied in accordance with the relevant instructions;
c) Performance as recorded during technical tests to check the levels or classes of protection provided by the PPE in guestion;
d) Suitable PPE accessories and the characteristics of appropriate spare parts;
e) The classes of protection appropriate to different levels of risk and the corresponding limits of use;
f) The obsolescence deadlineor period of obsolescence of PPEor certain of its components;
g) The type of packaging suitable for transport;
h) The significance of any markings(see 2.12)
i) Where appropriate the references of the Directives applied inaccordance with Article5(6) (b);
j) The name, address and identification number of the notified body involved in the design stage of the PPE

These notes, which must be precise and comprehensible, must be provided at least in the official language(s) of the member state of destination

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## 2. ADDITIONAL REQUIREMENTS COMMON TO SEVERAL CLASSES OR TYPES OF PPE

### 2.1. PPE incorporating adjustment systems

If PPE incorporates adjustment systems, the latter must be designed and manufactured so that, after adjustment, they do not become undone unintentionally in the foreseeable conditions of use.

### 2.3. PPE for the face, eyes and respiratory system

Any restriction of the user's face, eyes, field of vision or respiratory system by the PPE shall be minimised.
The screens for those types of PPE must have a degree of optical neutrality that is compatible with the degree of precision and the duration of the activities of the user.
If necessary, such PPE must be treated or provided with means to prevent misting-up.
Models of PPE intended for users requiring sight correction must be compatible with the wearing of spectacles or contact lenses.

### 2.4. PPE subject to ageing

If it is known that the design performance of new PPE may be significantly affected by 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.
If the manufacturer is unable to give an undertaking with regard to the useful life of the PPE, his instructions must provide all the information necessary to enable the purchaser or user to establish a reasonable obsolescence month and year, taking into account the quality level of the model and the effective conditions of storage, use, cleaning, servicing and maintenance.
Where appreciable and rapid deterioration in PPE performance is likely to be caused by ageing resulting from the periodic use of a cleaning process recommended by the manufacturer, the latter must, if possible, affix a marking to each item of PPE placed on the market indicating the maximum number of cleaning operations that may be carried out before the equipment needs to be inspected or discarded. Where such a marking is not affixed, the manufacturer must give that information in his instructions.

### 2.6. PPE for use in potentially explosive atmospheres

PPE intended for use in potentially explosive atmospheres must be designed and manufactured in such a way that it cannot be the source of an electric, electrostatic or impact-induced arc or spark likely to cause an explosive mixture to ignite.

### 2.8. PPE for intervention in very dangerous situations

The instructions supplied by the manufacturer with PPE for intervention in very dangerous situations must include, in particular, data intended for competent, trained persons who are qualified to interpret them and ensure their application by the user.
The instructions must also describe the procedure to be adopted in order to verify that PPE is correctly adjusted and functional when worn by the user.
Where PPE incorporates an alarm which is activated in the absence of the level of protection normally provided, the alarm must be designed and placed so that it can be perceived by the user in the foreseeable conditions of use.

### 2.9. PPE incorporating components which can be adjusted or removed by the user

Where PPE incorporates components which can be attached, adjusted or removed by the user for replacement purposes, such components must be designed and manufactured so that they can be easily attached, adjusted and removed without tools.

### 2.12. PPE bearing one or more identification or recognition marks directly or indirectly relating to health and safety

The identification or recognition marks directly or indirectly relating to health and safety affixed to these types or classes of must preferably take the form of harmonized pictograms or ideograms and must rem ain perfectly legible throughout the foreseeableuseful life of the PPE. In addition, these marks must be complete, precise and comprehensible so as to prevent any misinterpretation; in particular, where such marks incorporate words or sentences, the latter must appear in the official language(s) of the Member State where the equipment is to be used.
If PPE (or a PPE component) is too small to allow al lor part of the necessary marking to be affixed, the relevant information must be mentioned on the packing and in the manufacturer's notes.

## 3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS

### 3.10.1. Respiratory protection

PPE intended for the protection of the respiratory system must make it possible to supply the user with breathable air when exposed to a polluted atmosphere and/or an atmosphere having an inadequate oxygen concentration.
The breathable air supplied to the user by PPE must be obtained by appropriate means, for example after filtration of the polluted air through PPE or by supply from an external unpolluted source.
The constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure appropriate user respiration and respiratory hygiene for the period of wear concerned under the foreseeable conditions of use.
The leak-tightness of the facepiece and the pressure drop on inspiration and, in the case of the filtering devices, purification capacity must keep contaminant penetration from a polluted atmosphere low enough not to be prejudicial to the health or hygiene of the user.
The PPE must bear details of the specific characteristics of the equipment which, in conjunction with the instructions, enable a trained and qualified user to employ the PPE correctly.
In the case of filtering equipment, the manufacturer's instructions must also indicate the time limit for the storage of new filters kept in their original packaging.

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Technical Assessment of EN 149: 2001 + A1: 2009 Standard and other Standards it refers to, Clauses Corresponding to the (EU) 2016/425 Directive

## Conforming to EN 149:2001 + A1:2009 Standard Requirements

*Article* 5

**Classification:** Particle Filtering Half Mask
The mask subject to evaluation based on the test results and technical file provided by the manufacturer is classified as;
Filtering Efficiency and Maximum Total Inward Leakage: Classified as **FFP2**
Mask is classified for single shift use, **NR**

*Article* 7.4

**Packing:** Particle filtering half masks are packaged to protect them from contamination before use and with cardboard boxes to prevent mechanical damage. The packaging design and the product is considered to withstand the foreseeable conditions of use based on the visual inspection results given in the test report.

*Article* 7.5

**Material:** Materials used in particle filtering half masks, according to the simulated wearing treatment and temperature conditioning results; It is understood it withstands handling and wear over the period for which the particle filtering half mask is designed to be used, it suffered mechanical failure of the facepiece or straps, any material from the filter media released by the air flow through the filter has not constitute a hazard or nuisance for the wearer. The manufacturer declares that the materials used in manufacturing of the mask does not have an adverse affect to the health and safety of users.
Based on the test results, the masks did not collapse when subject to simulated wearing and temarature conditioning. No nuisance situation is reported during the practical performance tests by human subjects.

*Article* 7.6

**Cleaning and Disinfection:** Particle filtering half mask is **not** designed to be as re-usable. No cleaning or disinfection procedure provided by the manufacturer.

*Article* 7.7

**Practical Performance:**
The test report indicates that the human subjects did not face any difficulty in performing the excercises while they were weared by the sample masks, in walking test or work simulation tests. The wearers did not report any failure by means of head harness / straps/ earloops comfort, security of fastenings and field of vision. Also no imperfections reported during total inward tests about the comfort, field of vision and fastening issues.

| Assessed Elements | Positive | Negative | Requirements in accordance with EN 149:2001 + A1:2009 and Result |
|---|---|---|---|
| 2.Head harness comfort | 2 | 0 | Positive results are obtained from the test subjects **No imperfections** |
| 3.Security of fastenings | 2 | 0 | |
| 5.Field of vision | 2 | 0 | |

**Conditioning:** (A.R.) As Received, original

*Article* 7.8

**Finish of Parts:** Particle filtering half masks, which are likely to come into contact with the user, do not have sharp edges and do not contain burrs.

*Article* 7.9.1

**Total Inward Leakage:**

The Total Inward Leakage test is conducted by 10 individual in an aerosol chamber with a walking band, and samples are taken during the conduction of the excercises defined in the standard. The samples used in the test are subjected to the conditioning required in the standard as temperature conditioning and as received. The face dimensions of the subjects are also reported. The measurement details for each subject and for each excersize are available in the test report.

It was reported that:
All 50 exercise measurement results are smaller or equal to 11%, the values varies between 6,24% and 8,19%.
All 10 individual's arithmetic mean is smaller or equal to 8%, the values varies between 6,75% and 7,72%.

**According to the reported results, the product meets the limits for FFP2 classification.**

*Article* 7.9.2

**Penetration of filter material:** Sodium Chloride Testing

| Condition | No. of Sample | Sodium Chloride Testing 95 L/min max (%) | Requirements in accordance with EN 149:2001 + A1:2009 | Result |
|---|---|---|---|---|
| (A.R.) | 36 | 0,35 | FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 % | Filtering half masks fulfill the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in range of the **FFP1, FFP2 and FFP3** classes. |
| (A.R.) | 37 | 0,40 | | |
| (A.R.) | 38 | 0,39 | | |
| (S.W.) | 1 | 0,17 | | |
| (S.W.) | 2 | 0,41 | | |
| (S.W.) | 3 | 0,43 | | |
| (M.S. T.C.) | 10 | 0,22 | | |
| (M.S. T.C.) | 11 | 0,23 | | |
| (M.S. T.C.) | 12 | 0,38 | | |

**Conditioning:** (M.S.) Mechanical Strength
(T.C.) Temperature Conditioning
(A.R.) As Received, original
(S.W.) Simulated wearing treatment

95 L/min = 1,6 $dm^3.sn^{-1}$

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*Article* 7.9.2

**Penetration of filter material:** Paraffin Oil Testing

| Condition | No. of Sample | Paraffin Oil Testing 95 L/min max (%) | Requirements in accordance with EN 149:2001 + A1:2009 | Result |
|---|---|---|---|---|
| (A.R.) | 39 | 1,13 | FFP1 ≤ 20 %<br>FFP2 ≤ 6 %<br>FFP3 ≤ 1 % | Filtering half masks fulfill the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in range of the **FFP1 and FFP2** classes. |
| (A.R.) | 40 | 1,18 | | |
| (A.R.) | 41 | 1,30 | | |
| (S.W.) | 4 | 1,22 | | |
| (S.W.) | 5 | 1,02 | | |
| (S.W.) | 6 | 1,09 | | |
| (M.S. T.C.) | 13 | 1,26 | | |
| (M.S. T.C.) | 14 | 1,34 | | |
| (M.S. T.C.) | 15 | 1,24 | | |

**Conditioning:** (M.S.) Mechanical Strength
(T.C.) Temperature Conditioning
(A.R.) As Received, original
(S.W.) Simulated wearing treatment

*Article* 7.10

**Compatibility with skin:** In Practical Performance report, the likelihood of mask materials in contact with the skin causing irritation or other adverse effect on health was not reported.

*Article* 7.11

**Flammability:**

| Condition | No. of Sample | Visual inspection | Requirements in accordance with EN 149:2001 + A1:2009 | Result |
|---|---|---|---|---|
| (A.R.) | 45 | Burn for 0,2s | Filtering half mask shall not burn or not continue to burn for more than 5 s after removal from the flame | **Passed**<br>Filtering half masks fulfill requirements of the standard |
| (A.R.) | 46 | Burn for 0,2s | | |
| (T.C.) | 21 | Burn for 0,3s | | |
| (T.C.) | 22 | Burn for 0,2s | | |

**Conditioning:** (A.R.) As Received, original
(T.C.) Temperature Conditioning

*Article* 7.12

**Carbon dioxide content of the inhalation air:**

| Condition | No. of Sample | $CO_2$ content of the inhalation air [%] by volume | An average $CO_2$ content of the inhalation air | Requirements in accordance with EN 149:2001 + A1:2009 | Result |
|---|---|---|---|---|---|
| (A.R.) | 26 | 0,85 | 0,85[%] | $CO_2$ content of the inhalation air shall not exceed an average of 1,0% by volume | **Passed**<br>Filtering half masks fulfil requirements of the standard |
| (A.R.) | 27 | 0,88 | | | |
| (A.R.) | 28 | 0,81 | | | |

**Conditioning:** (A.R.) As Received, original

*Article* 7.13

**Head harness:** In Practical Performance and TIL test reports no adverse effects have been reported for donning and remove of the mask also the results of these tests indicates that the ear loops / head harness are capable of holding the mask firmly enough.

*Article* 7.14

**Field of vision:** In Practical Performance report, no adverse effects were reported for the field of vision availability when the mask is weared.

*Article* 7.15

**Exhalation Valve(s):** The model under inspection have no valves.

*Article* 7.16

**Breathing Resistance:** Inhalation

The overall evaluation in the figures gathered for 9 different samples 3 as received, 3 with temparature conditioning and 3 simulated wearing treatment conditioned complies with the limits given in the standard for FFP1, FFP2 and FFP3 classes. This is valid for inhalation results for 30 L/min, 95 L/min and exhalation at 160 L/min.

**Passed.**

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| | |
|---|---|
| *Article* 7.17 | **Clogging:** This test is not applied to Particle Filtering Half Mask which is not reusable.<br>***(For single shift use devices, the clogging test is optional test. For re-usable devices test is mandatory.)*** |
| *Article* 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. |
| *Article* 9 | **Marking – Packaging:** Necessary markings are available on the product package (box). The name and trademark of the manufacturer 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 year of end 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 Annex 9.1 of the technical file.<br><br>The technical documentation for mask design (drawing) also evaluated for marking requirements, drawing P0102. The mask template (drawing) indicates that the mask will carry information about the name and brandname (Budak Testil San.Tic.A.Ş./PROPAKS) of 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. Even the tested samples by the laboratory do not carry necessary marking information as stated in the technical documentation, the manufacturer shall follow marking instructions for serial production. Model P0102 drawing exists in the technical file of the manufacturer, Annex 6 of technical file. |
| *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, Annex 8. The manufacturer shall include this documented user information text in every smallest commertially available package. |

| PREPARED BY | APPROVED BY |
|---|---|
| **Osman CAMCI**<br>PPE Expert | **Suat KAÇMAZ**<br>Director<br>UNIVERSAL CERTIFICATION CE 2163 Notified Body |



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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:** 21.10.2020
**Report Number:** 10-2020-T0462

## CLIENT and SAMPLE INFORMATION

| | | | |
|---|---|---|---|
| TEST OWNER | BUDAK TESKTİL SAN. VE TİC. LTD. ŞTİ. | | |
| ADDRESS | Adnan Kahveci Mah. Gülyali Cad. No:4 Beylikdüzü İstanbul TURKEY | | |
| SAMPLE DESCRIPTION | Folding type protective mask | | |
| BRAND NAME – MODEL | P0102 | | |
| TESTING STANDARD | EN 149+A1:2009 | | |
| CASE NUMBER | CE-PPE-3505 | | |
| SAMPLE RECEIVE DATE | 15.09.2020 | TESTING START DATE | 15.09.2020 |
| DISINFECTION INSTRUCTION *If applicable* | Not given, single use only | | |
| NUMBER OF SAMPLES | 50 | SAMPLE IDs: | 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.

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Sarıgazi V.D. 892 025 8722
Suat KAÇMAZ
Director

## 1. *REPORT SUMMARY*

| *TEST STANDARD* | *TEST NAME* | *RESULT* | *EVALUATION* |
|---|---|---|---|
| EN 149:2001 + A1:2009 clause 8.5 EN 13274-1:2001 | Total Inward Leakage Testing | **Pass** | **FFP2** |
| 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 EN 13274-4:2001 | Flammability Testing | **Pass** | **See results** |
| 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 + A1:2009 clause 8.9 EN 13274-3:2001 | Breathing Inhalation Resistance-30 l/min | **Pass** | **See results** |
| | 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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Sarıgazi V.D. 892 025 8722

## 2. *TEST RESULTS and EVALUATION*

**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 ± 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 | 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

UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZM. TİC. LTD. ŞTİ.
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## 7.6 CLEANING AND DISINFECTING (EN 149:2001 + A1:2009 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.<br>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.<br><br>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. | No imperfections | Detail refer to Annex I |

**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<br>Head harness comfort<br>Security of fastenings<br>Field of vision | 2<br>2<br>2<br>2 | 0<br>0<br>0<br>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<br><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 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 149:2001 + A1:2009 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<br><br>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. | 7,32 | 6,56 | 6,24 | 6,41 | 7,24 | 6,75 |
| 2 | 32 | A.R. | 6,49 | 7,98 | 7,32 | 7,63 | 7,56 | 7,40 |
| 3 | 33 | A.R. | 6,98 | 7,96 | 7,93 | 8,12 | 7,62 | 7,72 |
| 4 | 34 | A.R. | 7,70 | 6,37 | 6,64 | 7,13 | 7,22 | 7,01 |
| 5 | 35 | A.R. | 6,82 | 8,17 | 8,14 | 6,87 | 7,09 | 7,42 |
| 6 | 16 | T.C. | 8,12 | 7,49 | 6,32 | 7,00 | 6,85 | 7,16 |
| 7 | 17 | T.C. | 7,89 | 6,65 | 7,63 | 7,36 | 7,96 | 7,50 |
| 8 | 18 | T.C. | 8,07 | 7,84 | 6,43 | 7,39 | 8,19 | 7,59 |
| 9 | 19 | T.C. | 8,16 | 6,40 | 8,07 | 8,16 | 7,06 | 7,57 |
| 10 | 20 | T.C. | 7,09 | 7,67 | 6,66 | 8,11 | 7,59 | 7,42 |
| All 50 individual exercise results were not greater than 11 %<br>All 10 individual wearer arithmetic means were not greater than 8 %. | | | | | | | | Pass (FFP2) |

| 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 MATERIAL (EN 149:2001 + A1:2009 clause 8.11)

**Test Method:** Described in Clause 8.11

<table>
<tr><th>REQUIREMENT</th><th>RESULTS</th><th>COMMENT</th></tr>
<tr><td>
<table>
<tr><td rowspan="2">Classification</td><td colspan="2">Max penetration of test aerosol</td></tr>
<tr><td>NaCl test<br>95 l/min<br>%max</td><td>Paraffin oil test<br>95 l/min<br>%max</td></tr>
<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>
</table>
</td><td>Pass</td><td>Detail refer to Annex IIIA and IIIB</td></tr>
</table>

**Annex IIIA-Test Result:**

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

<table>
<tr><th>No. of Sample</th><th>Condition</th><th>Penetration of Sodium Chloride in accordance with EN 13274-7:2019<br>[%]<br>Flow rate 95 l/min</th><th>Requirements in accordance with EN 149:2001+A1:2009</th><th>Assessment of Test Result Conformity / Nonconformity</th></tr>
<tr><td>36</td><td rowspan="3">As received</td><td>0,35</td><td rowspan="9">FFP1 ≤ 20 %<br><br>FFP2 ≤ 6 %<br><br>FFP3 ≤ 1 %</td><td rowspan="9">Passed<br><br>Filtering half masks fulfil the requirements of the standard EN 149:2001+A1:2009 given in 7.9.2 in range of the first, second protection class (FFP1, FFP2)</td></tr>
<tr><td>37</td><td>0,40</td></tr>
<tr><td>38</td><td>0,39</td></tr>
<tr><td>1</td><td rowspan="3">Simulated wearing treatment</td><td>0,17</td></tr>
<tr><td>2</td><td>0,41</td></tr>
<tr><td>3</td><td>0,43</td></tr>
<tr><td>10</td><td rowspan="3">Mechanical strength + Temperature conditioned</td><td>0,22</td></tr>
<tr><td>11</td><td>0,23</td></tr>
<tr><td>12</td><td>0,38</td></tr>
</table>

**Annex IIIB-Test Result:**

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

<table>
<tr><th>No. of Sample</th><th>Condition</th><th>Penetration of Paraffin Oil Mist in accordance with EN 13274-7:2019<br>[%]<br>Flow rate<br>95 l/min</th><th>Requirements in accordance with EN 149:2001+A1:2009</th><th>Assessment of Test Result Conformity / Nonconformity</th></tr>
<tr><td>39</td><td rowspan="3">As received</td><td>1,13</td><td rowspan="9">FFP1 ≤ 20 %<br><br>FFP2 ≤ 6 %<br><br>FFP3 ≤ 1 %</td><td rowspan="9">Passed<br><br>Filtering half masks fulfil the requirements of the standard EN 149:2001+A1:2009 given in 7.9.2 in range of the first, second protection classes (FFP1, FFP2)</td></tr>
<tr><td>40</td><td>1,18</td></tr>
<tr><td>41</td><td>1,30</td></tr>
<tr><td>4</td><td rowspan="3">Simulated wearing treatment</td><td>1,22</td></tr>
<tr><td>5</td><td>1,02</td></tr>
<tr><td>6</td><td>1,09</td></tr>
<tr><td>13</td><td rowspan="3">Mechanical strength + Temperature conditioned</td><td>1,26</td></tr>
<tr><td>14</td><td>1,34</td></tr>
<tr><td>15</td><td>1,24</td></tr>
</table>

Lab A + B

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## 7.10 COMPATIBILITY WITH SKIN (EN 149:2001 + A1:2009 clause 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 | As received | 0,2 s | Filtering half mask shall not burn or not continue to burn for more than 5 s after removal from the flame | Passed Filtering half masks fulfil requirements of the standard EN 149:2001 + A1:2009 given in 7.11 |
| 46 | | 0,2 s | | |
| 21 | Temperature conditioned | 0,3 s | | |
| 22 | | 0,2 s | | |

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 | As received | 0,85 | 0,85 | $CO_2$ content of the inhalation air shall not exceed an average of 1,0% by volume | Passed Filtering half masks fulfil requirements of the standard EN 149:2001 + A1:2009 given in 7.12 |
| 27 | | 0,88 | | | |
| 28 | | 0,81 | | | |

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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. |

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## 7.16 BREATHING RESISTANCE (EN 149:2001 + A1:2009 clause 8.9)

**Test Method:** Described in Clause 8.9

| REQUIREMENT | RESULTS | COMMENT |
|---|---|---|
| Classification / Max permitted resistance (mbar): Inhalation 30 l/min, 95 l/min; Exhalation 160 l/min. FFP1: 0.6, 2.1, 3.0; FFP2: 0.7, 2.4, 3.0; FFP3: 1.0, 3.0, 3.0 | Pass | Classified as FFP2<br>Detail refer to Annex VIA-VIB |

| Classification | Max 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 | 1.0 | 3.0 | 3.0 |

### Annex VIA-Test Result:

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

**Inhalation Resistance**

| No. of Sample | Condition | Inhalation Resistance (mbar) | | | | |
|---|---|---|---|---|---|---|
| | | Flow rate 30 l/min [mbar] | Requirements in accordance with EN 149:2001+A1:2009 | Flow rate 95 l/min [mbar] | Requirements in accordance with EN 149:2001+A1:2009 | Assessment of Test Result Conformity / Nonconformity |
| 42 | As received | 0,36 | FFP1 ≤ 0,60<br>FFP2 ≤ 0,70<br>FFP3 ≤ 1,0 | 1,62 | FFP1 ≤ 2,10<br>FFP2 ≤ 2,40<br>FFP3 ≤ 3,00 | Passed Qualifies FFP1, FFP2, FFP3 |
| 43 | | 0,41 | | 1,65 | | |
| 44 | | 0,36 | | 1,65 | | |
| 7 | Simulated wearing treatment | 0,43 | | 1,63 | | |
| 8 | | 0,39 | | 1,58 | | |
| 9 | | 0,37 | | 1,65 | | |
| 23 | Temperature conditioned | 0,36 | | 1,61 | | |
| 24 | | 0,42 | | 1,60 | | |
| 25 | | 0,44 | | 1,63 | | |

**Exhalation Resistance**

| No. of Sample | Condition | Flow rate | Facing directly | Facing vertically upwards | Facing vertically downwards | Lying on the left side | Lying on the right side | Requirements in accordance with EN 149:2001+A1:2009 | Assessment of Test Result Conformity / Nonconformity |
|---|---|---|---|---|---|---|---|---|---|
| 42 | As received | 160l/min | 2,23 | 2,23 | 2,33 | 2,23 | 2,24 | FFP1 ≤ 3,0<br>FFP2 ≤ 3,0<br>FFP3 ≤ 3,0 | Passed Qualifies FFP1, FFP2, FFP3 |
| 43 | | | 2,34 | 2,21 | 2,30 | 2,34 | 2,23 | | |
| 44 | | | 2,37 | 2,35 | 2,38 | 2,25 | 2,27 | | |
| 7 | Simulated wearing treatment | | 2,30 | 2,26 | 2,38 | 2,27 | 2,30 | | |
| 8 | | | 2,39 | 2,24 | 2,23 | 2,29 | 2,34 | | |
| 9 | | | 2,27 | 2,29 | 2,23 | 2,24 | 2,27 | | |
| 23 | Temperature conditioned | | 2,27 | 2,22 | 2,30 | 2,21 | 2,29 | | |
| 24 | | | 2,36 | 2,24 | 2,37 | 2,33 | 2,22 | | |
| 25 | | | 2,27 | 2,40 | 2,24 | 2,37 | 2,24 | | |

Lab A

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## 7.17 CLOGGING (EN 149:2001 + A1:2009 clause 8.9, 8.10)

**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. |

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

| Code | Laboratory Name | Competency Explanations |
|---|---|---|
| Lab A | UNIVERSAL SERTIFIKASYON VE 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. |

- The laboratories are contracted bodies with UNIVERSAL CERTIFICATION and the technical competence of the laboratories is also under supervision / assessment of UNIVERSAL CERTIFICATION based on the provisions of EN ISO/IEC 17065 Requirements for bodies certifying products, processes and services standard.
- Each test result given in this test report shown with the issuing laboratory code.

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**Sample Photo**


**- End of Report -**

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