MNA LABORATUVARLARI

Notified Body Number: 2841

# CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT CHECKS AT RANDOM INTERVALS (MODULE C2)

# MODÜL C2 - ÜRETİMİN DÂHİLÎ KONTROLÜ VE ÜRÜNÜN RASTGELE ARALIKLARLA DENETİMLİ MUAYENESİNE DAYALI TİPE UYGUNLUK

| | |
|---|---|
| **Belge No** / *Certificate No* | : 277-22-01-01 |
| **Belgelendirme Tarihi - Bir Sonraki Belge Tarihi** / *Certification Date / Certificate Validity Date* | : 22.08.2022/22.08.2023 |
| **Belge Geçerlilik Tarihi** / *Document Validity Period* | : 1 yıl / *1 year* |
| **Firma Unvanı ve Adresi** / *Company Name and Address* | : i-Access Protect GmbH<br>Riegeler Straße 4, 79364 Malterdingen, Germany |
| **Marka / Model** / *Brand / Model* | : Protect PRO |
| **Direktifi** / *Directive* | : 2016/425 REGULATION |
| **Modülü/Kategori** / *Module / Category* | : C2 MODÜLÜ/ KATEGORİ III<br>*MODULE C2 / CATEGORY III* |
| **Teknik Değerlendirme Rapor No**/ *Technical Evaluation Report No* | : 277-22-01-01 |
| **Ürün Tipi** / *Product Type:* | |

- EN 149:2001+ A1:2009 Solunumla ilgili koruyucu cihazlar - Parçacıklara karşı koruma amaçlı filtreli yarım maskeler/ *Respiratory protective devices - Filtering half masks to protect against particles*

**Ürünün Malzeme Bilgisi** / ***Product Material Information*:** Protect PRO model ürünleri kumaş, elastik kayış, burun klipsi, filtre katmanı kullanılarak imal edilmiştir Protect PRO *1.0 model products are manufactured using fabric, elastic strap, nose clip, filter layer.*

***Volkan AKIN***
***22.08.2022***
***Karar Verici / Approver***

***Okan AKEL***
***22.08.2022***
***Şirket Müdürü / General manager***

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# CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT CHECK AT RANDOM INTERVALS (MODULE C2, ANNEX VII) (277-22-01-01)

**Report No** : 277-22-01-01

**Report Date** : 22.08.2022

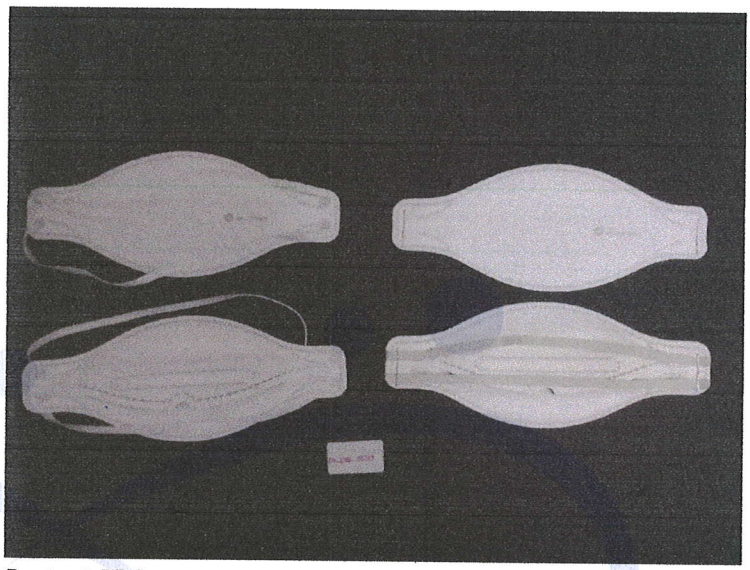
**Application No** : 277-22-01-01

1. **COMPANY INFORMATION:**
   i-Access Protect GmbH
   Riegeler Straße 4, 79364 Malterdingen, Germany

2. **PPE INFORMATION:**
   Disposable and non-sterile half mask made of particulate protection filter material.

3. **PPE TYPE IDENTIFICATION**
   EN 149:2001+A1:2009 Respiratory protective devices – Filtering half masks to protect against particles - Requirements, testing, marking

4. **PPE PICTURES**



Protect PRO

5. **PPE DIMENSIONS:**
   Protect PRO model has been found to be produced using standard sizes.

6. **PPE PRODUCT MATERIAL INFORMATION:**
   The mask is made of elastic strap, nonwoven fabric on the outer and inner layers and filter material on the middle layer.

7. **ESSENTIAL HEALTH AND SAFETY REQUIREMENTS**
   - A visual inspection was made according to EN 149:2001 +A1:2009 for ergonomics.
   - Protection levels and degrees are defined by the manufacturer.
   - Suitable construction materials were determined by visual inspection according to EN 149:2001 +A1:2009.

## 8. ANALYSIS EVALUATION AND MARKING:

**EN 149:2001 +A1:2009**

| TESTS | PARAMETER | PERFORMANCE LEVELS | | | RESULTS | PERFORMANCE LEVELS | EVALUATION |
|---|---|---|---|---|---|---|---|
| | | FFP1 | FFP2 | FFP3 | | | |
| Part 7.3 Visual inspection | Shall also the marking and the information supplied by the manufacturer | | | | Appropriate | - | PASS |
| Banned Azo Dyes | < 30 mg/kg | | | | Not applicable | - | Not applicable |
| Part 7.4 Packaging | Particle filtering half mask shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use. | | | | Appropriate | - | PASS |
| Part 7.5 Material | When conditioned in accordance 8.3.1 & 8.3.2 the particle filter half mask shall not collapse. | | | | Appropriate | - | PASS |
| Part 7.6 Cleaning and disinfecting | After cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class. | | | | Not applicable | - | Not applicable |
| Part 7.7 Practical performance | No negative comments should be made by the test subject regarding any of the criteria evaluated. | | | | Appropriate | - | PASS |
| Part 7.8 Finish of parts | Parts of the device likely to come into contact with the wearer shall have no sharp edge or burrs. | | | | Appropriate | - | PASS |

| TESTS | PARAMETER | PERFORMANCE LEVELS | | | RESULTS | PERFORMANCE LEVELS | EVALUATION |
|---|---|---|---|---|---|---|---|
| | | FFP1 | FFP2 | FFP3 | | | |
| Part 7.9.1 Total inward leakage | At least 46 out of the 50 individual exercise result | ≤25 | ≤11 | ≤5 | See the table below | FFP2 | PASS |
| | At least 8 out of the 10 individual wearer arithmetic means | ≤22 | ≤8 | ≤2 | See the table below | FFP2 | PASS |

| Total Inward Leakage (%) | | | | | | |
|---|---|---|---|---|---|---|
| | Exercise 1 | Exercise 2 | Exercise 3 | Exercise 4 | Exercise 5 | Average |
| Subject 1 (As received) | 2,0 | 3,9 | 3,7 | 4,5 | 3,1 | 3,4 |
| Subject 2 (As received) | 3,8 | 3,3 | 4,3 | 6,3 | 4,3 | 4,4 |
| Subject 3 (As received) | 3,5 | 3,0 | 4,1 | 7,0 | 5,0 | 4,5 |
| Subject 4 (As received) | 4,6 | 5,0 | 2,9 | 6,4 | 6,6 | 5,1 |
| Subject 5 (As received) | 4,8 | 2,0 | 4,1 | 6,3 | 4,3 | 4,3 |
| Subject 6 (After temperature conditioning) | 4,2 | 4,6 | 1,8 | 6,8 | 6,0 | 4,7 |

| | | | | | | |
|---|---|---|---|---|---|---|
| Subject 7 (After temperature conditioning) | 4,4 | 5,2 | 4,0 | 4,2 | 6,3 | 4,8 |
| Subject 8 (After temperature conditioning) | 3,7 | 4,0 | 5,2 | 4,1 | 5,0 | 4,4 |
| Subject 9 (After temperature conditioning) | 3,6 | 3,8 | 3,7 | 4,2 | 5,6 | 4,2 |
| Subject 10 (After temperature conditioning) | 4,4 | 3,6 | 3,4 | 5,7 | 3,7 | 4,2 |

**Subject facial dimensions**

| Subject | Face Length (mm) | Face Width (mm) | Face Depth (mm) | Mouth Width (mm) |
|---|---|---|---|---|
| 1 | 133 | 132 | 132 | 65 |
| 2 | 125 | 144 | 116 | 67 |
| 3 | 126 | 135 | 124 | 75 |
| 4 | 123 | 133 | 134 | 74 |
| 5 | 117 | 135 | 122 | 73 |
| 6 | 122 | 142 | 133 | 66 |
| 7 | 113 | 132 | 114 | 75 |
| 8 | 135 | 123 | 123 | 65 |
| 9 | 122 | 135 | 133 | 74 |
| 10 | 135 | 142 | 125 | 83 |

| TESTS | PARAMETER | PERFORMANCE LEVELS | | | RESULTS | PERFORMANCE LEVELS | EVALUATION |
|---|---|---|---|---|---|---|---|
| | | FFP1 | FFP2 | FFP3 | | | |
| Part 7.9.2 Penetration of filter material | Sodium chloride, 95 L/min %, max | % 20 | % 6 | % 1 | See the table below | FFP2 | PASS |
| | Paraffin oil, 95 L/min %, max | % 20 | % 6 | % 1 | See the table below | FFP2 | PASS |

| Penetration of filter material | Sodium Chloride (%) | Paraffin Oil (%) |
|---|---|---|
| As received | 1,3 | 1,2 |
| As received | 1,3 | 1,3 |
| As received | 1,1 | 1,2 |
| After the simulated wearing treatment | 1,5 | 1,6 |
| After the simulated wearing treatment | 1,6 | 1,5 |
| After the simulated wearing treatment | 1,4 | 1,6 |
| Mechanical strength and temperature conditioning | 3,2 | 3,7 |
| Mechanical strength and temperature conditioning | 2,9 | 3,5 |
| Mechanical strength and temperature conditioning | 2,9 | 3,5 |

| TESTS | PARAMETER | PERFORMANCE LEVELS | | | RESULTS | PERFORMANCE LEVELS | EVALUATION |
|---|---|---|---|---|---|---|---|
| | | FFP1 | FFP2 | FFP3 | | | |
| Part 7.10 Compatibility with skin | Materials shall not be known to be likely to cause irritation or any other adverse effect to health | | | | Appropriate | - | PASS |
| Part 7.11 Flammibility | Mask shall not burn or not to continue to burn for more than 5 s | | | | Flame not seen | - | PASS |
| Part 7.12 | Shall not exceed an average of % 1 | | | | 0,70<br>0,71 | - | PASS |

| | | | | |
|---|---|---|---|---|
| Carbondioxide content of the inhalation air | | 0,71 | | |
| Part 7.13 Head harness | It can be donned and removed easily | Appropriate | - | PASS |
| Part 7.14 Field of vision | The field of vision shall acceptable in practical performance test. | Appropriate | - | PASS |
| Part 7.15 Exhalation valve(s) | It shall withstand axially a tensile force of 10 N apply for 10 s.<br>If fitted, shall continue to operate correctly after a continuous exhalation flow of 300 L/min over a period of 30 s. | Not applicable | - | Not applicable |

| TESTS | PARAMETER | PERFORMANCE LEVELS | | | RESULTS | PERFORMANCE LEVELS | EVALUATION |
|---|---|---|---|---|---|---|---|
| | | FFP1 | FFP2 | FFP3 | | | |
| Part 7.16 Breathing Resistance | Inhalation 30L/min | 0,6 mbar | 0,7 mbar | 1,0 mbar | See the table below | FFP2 | PASS |
| | Inhalation 95L/min | 2,1 mbar | 2,4 mbar | 3,0 mbar | See the table below | FFP2 | PASS |
| | Exhalation 160L/min | 3,0 mbar | 3,0 mbar | 3,0 mbar | See the table below | FFP2 | PASS |

| Breathing Resistance (mbar) | Inhalation 30L/min | Inhalation 95L/min |
|---|---|---|
| As received | 0,4 | 1,4 |
| As received | 0,4 | 1,4 |
| As received | 0,4 | 1,4 |
| After temperature conditioning | 0,3 | 1,3 |
| After temperature conditioning | 0,3 | 1,3 |
| After temperature conditioning | 0,3 | 1,3 |
| After the simulated wearing treatment | 0,3 | 1,3 |
| After the simulated wearing treatment | 0,4 | 1,4 |
| After the simulated wearing treatment | 0,4 | 1,3 |
| After the flow conditioning | - | - |
| After the flow conditioning | - | - |
| After the flow conditioning | - | - |

| Breathing Resistance 160L/min (mbar) | Facing directly ahead | Facing vertically upwards | Facing vertically downwards | Lying on the left side | Lying on the right side |
|---|---|---|---|---|---|
| As received | 2,2 | 2,1 | 2,2 | 2,2 | 2,2 |
| As received | 2,1 | 2,2 | 2,2 | 2,1 | 2,2 |
| As received | 2,1 | 2,1 | 2,1 | 2,2 | 2,2 |
| After temperature conditioning | 2,1 | 2,1 | 2,2 | 2,1 | 2,1 |
| After temperature conditioning | 2,2 | 2,1 | 2,1 | 2,1 | 2,1 |
| After temperature conditioning | 2,2 | 2,1 | 2,1 | 2,1 | 2,1 |
| After the simulated wearing treatment | 2,2 | 2,1 | 2,2 | 2,1 | 2,1 |
| After the simulated wearing treatment | 2,1 | 2,1 | 2,1 | 2,2 | 2,1 |

| | | | | | |
|---|---|---|---|---|---|
| After the simulated wearing treatment | 2,1 | 2,1 | 2,1 | 2,1 | 2,1 |
| After the flow conditioning | - | - | - | - | - |
| After the flow conditioning | - | - | - | - | - |
| After the flow conditioning | - | - | - | - | - |

| TESTS | PARAMETER | PERFORMANCE LEVELS | | | RESULTS | PERFORMANCE LEVELS | EVALUATION |
|---|---|---|---|---|---|---|---|
| | | FFP1 | FFP2 | FFP3 | | | |
| Part 7.17 Clogging | After clogging the inhalation resistances shall not exceed. (valved) | 4 mbar | 5 mbar | 7 mbar | Not applicable | - | Not applicable |
| | The exhalation resistance shall not exceed 3 mbar at 160 L/ min continuous flow. (valved) | | | | Not applicable | - | Not applicable |
| | After clogging the inhalation and exhalation resistances shall not exceed. (valveless) | 3 mbar | 4 mbar | 5 mbar | Not applicable | - | Not applicable |
| Part 7.18 Demountable part | All demountable parts (if fitted) shall be readily connected and secured were possible by hand. | | | | Not applicable | - | Not applicable |
| Part 9 Marking | The packaging information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent. | | | | Appropriate | - | PASS |

## 9. DECISION

Analysis and examinations Protect PRO model coded personal protective equipment; Respiratory Protective Devices EN 149:2001 +A1:2009- Filtered Half Masks for Protection Against Particles - Properties, Experiments and Marking standards are evaluated. The homogeneity of the production was monitored at the performance levels determined as a result of the technical evaluations made within the scope of MODULE C2.

## 10. ATTACHMENTS

- Basic Health Safety Requirements
- Risk Assessment
- Test Reports (M-2022-0599)
- User Instruction

**CONTROLLER** : **VOLKAN AKIN**

**SIGNATURE** :

**DATE** : **22.08.2022**

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# ANALYSIS REPORT

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| | |
|---|---|
| Purpose of Analysis | : Special request |
| Sample Send Org. | : i-Access Protect GmbH |
| Address | : Riegeler Straße 14 |
| Sample Acceptance Date | : 2022-07-28 16:48:12 |
| Analysis Date | : 2022-07-28 17:43:32 |
| Sample Quantity | : 80 Pieces |
| Sample Description | : Protect Pro F20 / Protect Pro R20 |
| Other informations | : |

## Flammability

| Tests | Analysis result | Limit Value | Method | Evaluation | Physical Condition |
|---|---|---|---|---|---|
| **Flammability** | **No flame seen.** | **Shall not burn for more than 5 sec after removal from the flame** | **EN 13274-4** | **PASS** | **-** |

## Penetration Of Filter Material

| Tests | Analysis result | Limit Value | Method | Evaluation | Physical Condition |
|---|---|---|---|---|---|
| **Penetration Of Filter Material** | **Check the table.** | **FFP1≤20 FFP2≤6 FFP3≤1** | **EN 149+A1 Part 8.11, EN 13274-7** | **PASS (FFP2)** | **-** |

| | Sodium Chloride (%) | Paraffin Oil (%) |
|---|---|---|
| **As received 1** | **1,3** | **1,2** |
| **As received 2** | **1,3** | **1,3** |
| **As received 3** | **1,1** | **1,2** |
| **After the simulated wearing treatment 1** | **1,5** | **1,6** |
| **After the simulated wearing treatment 2** | **1,6** | **1,5** |
| **After the simulated wearing treatment 3** | **1,4** | **1,6** |
| **Mechanical strength and temperature conditioning (120 mg) 1** | **3,2** | **3,7** |
| **Mechanical strength and temperature conditioning (120 mg) 2** | **2,9** | **3,5** |
| **Mechanical strength and temperature conditioning (120 mg) 3** | **2,9** | **3,5** |



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## Carbon Dioxide Content Of The Inhalation Air

| Tests | Analysis result | Limit Value | Method | Evaluation | Physical Condition |
|---|---|---|---|---|---|
| **Carbon Dioxide Content Of The Inhalation Air** | **Check the table.** | **Maximum %1** | **EN 149+A1 Part 8.7** | **PASS (FFP2)** | **-** |

| | CO2 (%) |
|---|---|
| **Sample 1** | **0,70** |
| **Sample 2** | **0,71** |
| **Sample 3** | **0,71** |

## Breathing Resistance

| Tests | Analysis result | Limit Value | Method | Evaluation | Physical Condition |
|---|---|---|---|---|---|
| **Breathing Resistance** | **Check the table.** | **See the limits table.** | **EN 149+A1 Part 8.9** | **PASS (FFP2)** | **-** |

| Classification | 30 L/min max basınç (mbar) | 95 L/min max basınç (mbar) | 160 L/min max basınç (mbar) |
|---|---|---|---|
| **FFP1** | **0,6** | **2,1** | **3,0** |
| **FFP2** | **0,7** | **2,4** | **3,0** |
| **FFP3** | **1,0** | **3,0** | **3,0** |

| Inhalation | 30 L/min | 95 L/min |
|---|---|---|
| **As received 1** | **0,4** | **1,4** |
| **As received 2** | **0,4** | **1,4** |
| **As received 3** | **0,4** | **1,4** |
| **After temperature conditioning 1** | **0,3** | **1,3** |
| **After temperature conditioning 2** | **0,3** | **1,3** |
| **After temperature conditioning 3** | **0,3** | **1,3** |
| **After the simulated wearing treatment 1** | **0,3** | **1,3** |
| **After the simulated wearing treatment 2** | **0,4** | **1,4** |
| **After the simulated wearing treatment 3** | **0,4** | **1,3** |
| **After the flow conditioning 1** | **-** | **-** |



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| | | |
|---|---|---|
| **After the flow conditioning 2** | **-** | **-** |
| **After the flow conditioning 3** | | |

| Exhalation 160L/min | Facing directly ahead | Facing vertically upwards | Facing vertically downwards | Lying on the left side | Lying on the right side |
|---|---|---|---|---|---|
| **As received 1** | **2,2** | **2,1** | **2,2** | **2,2** | **2,2** |
| **As received 2** | **2,1** | **2,2** | **2,2** | **2,1** | **2,2** |
| **As received 3** | **2,1** | **2,1** | **2,1** | **2,2** | **2,2** |
| **After temperature conditioning 1** | **2,1** | **2,1** | **2,2** | **2,1** | **2,1** |
| **After temperature conditioning 2** | **2,2** | **2,1** | **2,1** | **2,1** | **2,1** |
| **After temperature conditioning 3** | **2,2** | **2,1** | **2,1** | **2,1** | **2,1** |
| **After the simulated wearing treatment 1** | **2,2** | **2,1** | **2,2** | **2,1** | **2,1** |
| **After the simulated wearing treatment 2** | **2,1** | **2,1** | **2,1** | **2,2** | **2,1** |
| **After the simulated wearing treatment 3** | **2,1** | **2,1** | **2,1** | **2,1** | **2,1** |
| **After the flow conditioning 1** | **-** | **-** | **-** | **-** | **-** |
| **After the flow conditioning 2** | **-** | **-** | **-** | **-** | **-** |
| **After the flow conditioning 3** | | | | | |

## Total Inward Leakage

| Tests | Analysis result | Limit Value | Method | Evaluation | Physical Condition |
|---|---|---|---|---|---|
| **Total Inward Leakage** | **Check the table.** | **See the limits table.** | **EN 149+A1 Part 8.5** | **PASS (FFP2)** | **-** |

| | At least 46 out of the 50 individual exercise result shall be not greater than | At least 8 out of the 10 individual wearer arithmetic means shall be not greater than |
|---|---|---|
| **FFP1** | **≤25** | **≤22** |
| **FFP2** | **≤11** | **≤8** |
| **FFP3** | **≤5** | **≤2** |

| | Exercise 1 | Exercise 2 | Exercise 3 | Exercise 4 | Exercise 5 | Average |
|---|---|---|---|---|---|---|




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| | | | | | | |
|---|---|---|---|---|---|---|
| **Subject 1 (As received)** | **2,0** | **3,9** | **3,7** | **4,5** | **3,1** | **3,4** |
| **Subject 2 (As received)** | **3,8** | **3,3** | **4,3** | **6,3** | **4,3** | **4,4** |
| **Subject 3 (As received)** | **3,5** | **3,0** | **4,1** | **7,0** | **5,0** | **4,5** |
| **Subject 4 (As received)** | **4,6** | **5,0** | **2,9** | **6,4** | **6,6** | **5,1** |
| **Subject 5 (As received)** | **4,8** | **2,0** | **4,1** | **6,3** | **4,3** | **4,3** |
| **Subject 6 (After temperature conditioning)** | **4,2** | **4,6** | **1,8** | **6,8** | **6,0** | **4,7** |
| **Subject 7 (After temperature conditioning)** | **4,4** | **5,2** | **4,0** | **4,2** | **6,3** | **4,8** |
| **Subject 8 (After temperature conditioning)** | **3,7** | **4,0** | **5,2** | **4,1** | **5,0** | **4,4** |
| **Subject 9 (After temperature conditioning)** | **3,6** | **3,8** | **3,7** | **4,2** | **5,6** | **4,2** |
| **Subject 10 (After temperature conditioning)** | **4,4** | **3,6** | **3,4** | **5,7** | **3,7** | **4,2** |



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***The analysis is within the scope of accreditation.**

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**5. Results are valid for the sample received.**
**6. A decision rule is a rule that determines how measurement uncertainty is to be taken into account when specifying compliance with a specified specification.TLM-052 Decision Rule According to the implementation instruction, the decision rule chosen in agreement with the customer will be applied if necessary.**
**7. Limit Values are determined by taking from analysis methods.**
**8. The laboratory is not responsible if the information provided by the CUSTOMER affects the validity of the results.**
**9. Test and / or measurement results, expanded measurement uncertainties (if any) and test methods are given in the following pa ges, which are the supplementary part of this certificate.**
**10. Water Repellency Determination Hydrostatic Pressure Determination T S ISO 811 (Hydrostatic Pressure Tester E / N: 53) Analysis, Seam Strength EN ISO 13965-2 (Strength Test Device E / N: 50) Analysis and resistance to liquid chemical permeation TS EN 659 -A1 Part 3.18 (Liquid Chemical Transfer Device E / N: 107) Analysis is carried out in the conditioning room and ISO 139 PART 3.2 conditions (23 ± 2 ° C temperature and 50 ± 4% relative humidity) are applied for ambient conditions.**

**Selin Gergin**

**Sample Acceptance and Reporting Officer**

**2022-08-22 13:36:46**

**Erhan Üstünel**

**Laboratory Responsible**

**2022-08-22 09:17:08**

**VOLKAN AKIN**

**Laboratory Manager**

**2022-08-22 13:04:34**



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