

# AB Tip İnceleme Sertifikası EU Type-Examination Certificate

**Belge No / Certificate No** : 147-21-04-R01  
**Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /  
Certification Date / Certificate Validity Date** : 06.04.2022-12.11.2026  
**Belge Geçerlilik Tarihi / Document Validity Period** : 5 yıl / 5 years  
**Firma Unvanı ve Adresi /  
Company Name and Address** : DESANTE ELEKTRONİK TEKNOLOJİ DİŞ  
TİC. A.Ş.  
Beşyol Mah. Karadeniz Sk. Polaris Tekstil Blok No:  
4 İçk: 4 Küçükçekmece / İSTANBUL  
**Ürün Adı /Modeller / Product Name / Models** : RM-3  
**Direktifi / Directive** : 2016/425 REGULATION  
**Modülü/Kategori / Module / Category** : B MODÜLÜ/ KATEGORİ III  
MODULE B / CATEGORY III  
**Teknik Değerlendirme Rapor No/  
Technical Evaluation Report No** : MNA 147-21-04-R01

**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:** RM-3 model ürünleri kumaş, elastik kayış, burun klipsi ve filtre katmanı kullanılarak imal edilmiştir./ RM-3 model products are manufactured using fabric, elastic strap, nose clip, exhalation valve, filter layer.

**Revizyon Nedeni / Reason for Revision :** Maske bedenine small beden eklenmiştir. / Small size has been added to mask sizes.

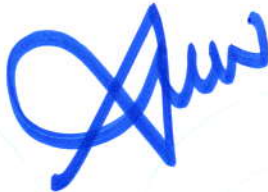
**Volkan AKIN**  
06.04.2022

**Karar Verici / Approver**



**Okan AKEL**  
06.04.2022

**Şirket Müdürü / General manager**



MNA Laboratuvarları San. Tic.Ltd .Şti

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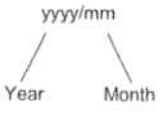

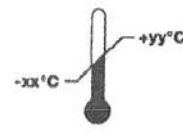

**ATTACHMENTS (147-21-04-R01)**

To certify the PPE product at Category III level, C2 or D module is accompanied by applying one of the conformity assessment methods along with the EU Type Examination (Module B).

**Model : RM-3**

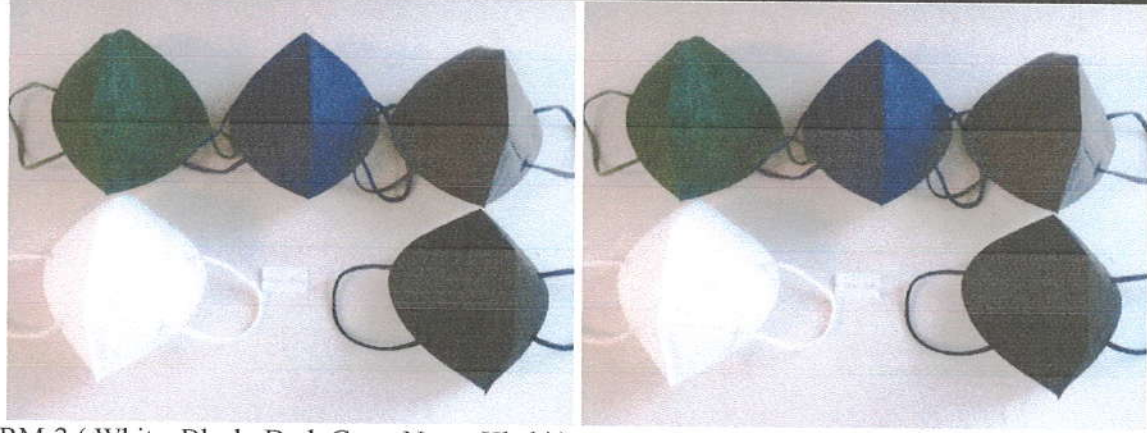
| PPE SPECIFICATION           | PERFORMANCE LEVELS |
|-----------------------------|--------------------|
| Classification              | FFP3               |
| Reusable / Single Shift Use | NR                 |

PPE produced as a single unit to fit an individual user, all the necessary instructions for manufacturing such PPE on the basis of the approved basic model:

| MARKING   |   |
|---|---|
| <b>MANUFACTURER:</b> DESANTE ELEKTRONİK TEKNOLOJİ DIŞ TİC. A.Ş.   |   |
| <b>PPE TYPE:</b>  |   |
| - EN 149:2001+ A1:2009 Respiratory protective devices - Filtering half masks to protect against particles |   |
| <b>MODEL:</b> RM-3  |   |
| <b>PRODUCT SIZE:</b> Standard and Small   |   |
| <b>PICTOGRAM AND PERFORMANCE LEVELS:</b>  |   |
| EN 149:2001+ A1:2009 FFP3 NR  |   |
|                        |    |
|                        |    |
|                      |  |
| NB 2841   |   |
| Or Condition of Storage   |   |

MNA LABORATORIES SAN. TIC. LTD. ŞTİ declares that the above-mentioned product meets the requirements of the directive according to the EU Directive 2016/425, the safety of the product is covered by the conditions and use specified in this certificate and in the technical file.



**ATTACHMENTS (147-21-04-R01)****PRODUCT PICTURES**

RM-3 ( White, Black, Dark Grey, Navy, Khaki )

**DOCUMENTS IN THE TECHNICAL FILE**

- Basic Health Safety Requirements
- Risk Assessment
- Test Reports
- Technical Report

Report No : 147-21-04-R01

Report Date : 06.04.2022

Application No : 147-21-04

**1. COMPANY INFORMATION:**

DESANTE ELEKTRONİK TEKNOLOJİ DİŞ TİC. A.Ş.

Beşyol Mah. Karadeniz Sk. Polaris Tekstil Blok No: 4 İçk: 4 Küçükçekmece / İSTANBUL

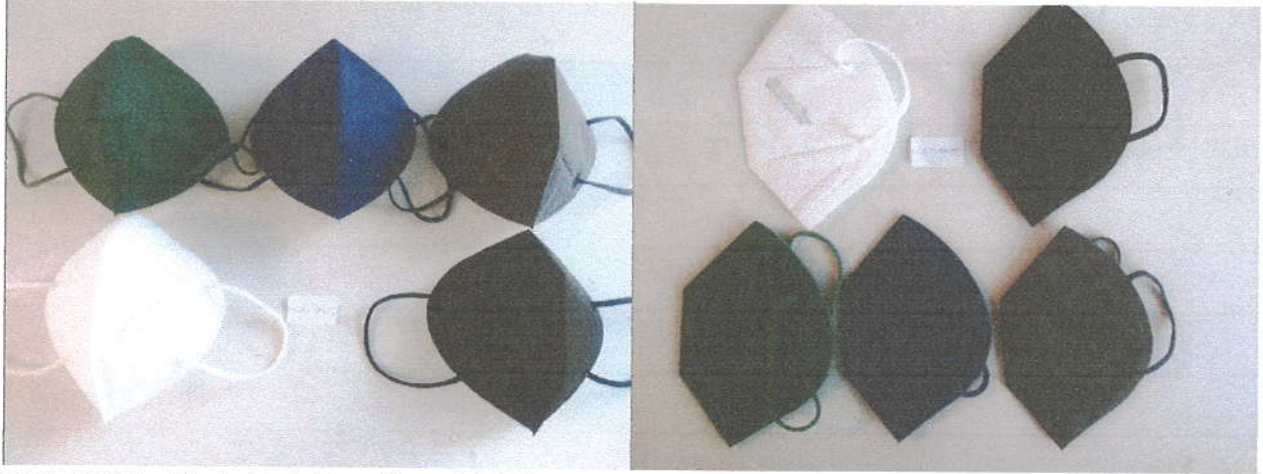
**2. PPE INFORMATION:**

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**



RM-3 ( White, Black, Dark Grey, Navy, Khaki )

**5. PPE DIMENSIONS:**

RM-3 model has been found to be produced using standard and small sizes.

**6. PPE PRODUCT MATERIAL INFORMATION:**

The product 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 AND EVALUATIONS:

EN 149:2001 +A1:2009

| TESTS                                 | PARAMETER   | PERFORMANCE LEVELS |      |      | RESULTS  | PERFORMANCE LEVELS | EVALUATION     |
|---------------------------------------|---|--------------------|------|------|--|--------------------|----------------|
|                                       |   | FFP1               | FFP2 | FFP3 |  |                    |                |
| Part 7.3<br>Visual inspection         | Shall also the marking and the information supplied by the manufacturer   |                    |      |      | Appropriate  | -                  | PASS           |
| Banned Azo Dyes                       | < 30 mg/kg  |                    |      |      | <5 mg/kg<br>( White, Black, Dark Grey, Navy, Khaki ) | -                  | PASS           |
| Part 7.4<br>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<br>Material                  | When conditioned in accordance 8.3.1 & 8.3.2 the particle filter half mask shall not collapse.  |                    |      |      | Appropriate  | -                  | PASS           |
| Part 7.6<br>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<br>Practical performance     | No negative comments should be made by the test subject regarding any of the criteria evaluated.  |                    |      |      | Appropriate  | -                  | PASS           |
| Part 7.8<br>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<br>Total inward leakage | At least 46 out of the 50 individual exercise result        | ≤25                | ≤11  | ≤5   | See the table below | FFP3               | PASS       |
|                                    | At least 8 out of the 10 individual wearer arithmetic means | ≤22                | ≤8   | ≤2   | See the table below | FFP3               | PASS       |

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

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

#### 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 | FFP3               | PASS       |
|   | Paraffin oil, 95 L/min % max    | % 20               | % 6  | % 1  | See the table below | FFP3               | PASS       |

| Penetration of filter material                   | Sodium Chloride (%) | Paraffin Oil (%) |
|--|---------------------|------------------|
| As received                                      | 0,3                 | 0,4              |
| As received                                      | 0,3                 | 0,3              |
| As received                                      | 0,3                 | 0,4              |
| After the simulated wearing treatment            | 0,4                 | 0,5              |
| After the simulated wearing treatment            | 0,3                 | 0,5              |
| After the simulated wearing treatment            | 0,2                 | 0,4              |
| Mechanical strength and temperature conditioning | 0,5                 | 0,7              |
| Mechanical strength and temperature conditioning | 0,5                 | 0,8              |
| Mechanical strength and temperature conditioning | 0,6                 | 0,7              |

| TESTS | PARAMETER | PERFORMANCE LEVELS |      |      | RESULTS | PERFORMANCE LEVELS | EVALUATION |
|-------|-----------|--------------------|------|------|---------|--------------------|------------|
|       |           | FFP1               | FFP2 | FFP3 |         |                    |            |



|  |   |                      |   |                |
|--|---|----------------------|---|----------------|
| Part 7.10<br>Compatibility<br>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<br>Flammibility                                      | Mask shall not burn or not to continue to burn for more than 5 s  | Flame not seen       | - | PASS           |
| Part 7.12<br>Carbondioxide<br>content of the<br>inhalation air | Shall not exceed an average of % 1  | 0,72<br>0,77<br>0,75 | - | PASS           |
| Part 7.13<br>Head harness                                      | It can be donned and removed easily   | Appropriate          | - | PASS           |
| Part 7.14<br>Field of vision                                   | The field of vision shall acceptable in practical performance test.   | Appropriate          | - | PASS           |
| Part 7.15<br>Exhalation<br>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<br>Breathing<br>Resistance | Inhalation 30L/min  | 0,6 mbar           | 0,7 mbar | 1,0 mbar | See the table below | FFP3               | PASS       |
|                                      | Inhalation 95L/min  | 2,1 mbar           | 2,4 mbar | 3,0 mbar | See the table below | FFP3               | PASS       |
|                                      | Exhalation 160L/min | 3,0 mbar           | 3,0 mbar | 3,0 mbar | See the table below | FFP3               | PASS       |

| Breathing Resistance (mbar)           | Inhalation 30L/min | Inhalation 95L/min |
|---------------------------------------|--------------------|--------------------|
| As received                           | 0,5                | 1,8                |
| As received                           | 0,5                | 1,7                |
| As received                           | 0,4                | 1,7                |
| After temperature conditioning        | 0,4                | 1,8                |
| After temperature conditioning        | 0,5                | 1,7                |
| After temperature conditioning        | 0,4                | 1,7                |
| After the simulated wearing treatment | 0,4                | 1,7                |
| After the simulated wearing treatment | 0,4                | 1,8                |
| After the simulated wearing treatment | 0,5                | 1,7                |

| 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                          | 2,8                   | 2,9                       | 2,8                         | 2,9                    | 2,9                     |
| As received                          | 2,9                   | 2,9                       | 2,8                         | 2,9                    | 2,9                     |
| As received                          | 2,8                   | 2,8                       | 2,8                         | 2,8                    | 2,9                     |
| After temperature conditioning       | 2,9                   | 2,9                       | 2,9                         | 2,9                    | 2,8                     |
| After temperature conditioning       | 2,9                   | 2,8                       | 2,9                         | 2,8                    | 2,9                     |
| After temperature conditioning       | 2,9                   | 2,9                       | 2,8                         | 2,9                    | 2,9                     |

|                                       |     |     |     |     |     |
|---------------------------------------|-----|-----|-----|-----|-----|
| After the simulated wearing treatment | 2,8 | 2,8 | 2,9 | 2,9 | 2,8 |
| After the simulated wearing treatment | 2,9 | 2,8 | 2,8 | 2,9 | 2,9 |
| After the simulated wearing treatment | 2,9 | 2,9 | 2,9 | 2,9 | 2,8 |

| TESTS                         | PARAMETER   | PERFORMANCE LEVELS |        |        | RESULTS        | PERFORMANCE LEVELS | EVALUATION     |
|-------------------------------|---|--------------------|--------|--------|----------------|--------------------|----------------|
|                               |   | FFP1               | FFP2   | FFP3   |                |                    |                |
| Part 7.17<br>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<br>Demountable part | All demountable parts (if fitted) shall be readily connected and secured were possible by hand.   |                    |        |        | Not applicable | -                  | Not applicable |
| Part 9<br>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 PROPOSAL

Analysis and examinations RM-3 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. It is recommended to be certified at the performance levels specified as a result of technical evaluations.

## 10. ATTACHMENTS

- Basic Health Safety Requirements
- Risk Assessment
- Test Report (M-2021-01574)
- User Instruction

Reason for revision : Small sized has been added.

CONTROLLER : VOLKAN AKIN

SIGNATURE :

DATE : 06.04.2022

