

**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** : 33-20-02-R01-01  
**Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /  
Certification Date / Certificate Validity Date** : 30.04.2021-30.04.2022  
**Belge Geçerlilik Tarihi / Document Validity Period** : 1 yıl / 1 years  
**Firma Unvanı ve Adresi /  
Company Name and Address** : METALSUD LO GATTO SRL  
Zona Industriale Loc. Aeroporto 89900 Vibo  
Valentia (VV) ITALY

**Ürün Adı /Modeller / Product Name / Models** : SICURA P30  
**Direktifi / Directive** : 2016/425 REGULATION  
**Modülü/Kategori / Module / Category** : C2 MODÜLÜ/ KATEGORİ III  
MODULE C2 / CATEGORY III  
**Test Rapor No/ları / Test Report No** : M-2021-00746  
**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:** SICURA P30 model ürünleri kumaş, elastik kayış, burun klipsi ve filtre katmanı kullanılarak imal edilmiştir./ SICURA P30 model products are manufactured using fabric, elastic strap, nose clip, filter layer.

**Erhan ÜSTÜNEL**  
30.04.2021  
Karar Verici / Approver



**Okan AKEL**  
30.04.2021  
Şirket Müdürü / General manager





Report No : 33-20-02-R01-01

Report Date : 30.04.2021

Application No : 33-20-02-R01-01

**1. COMPANY INFORMATION:**

METALSUD LO GATTO SRL

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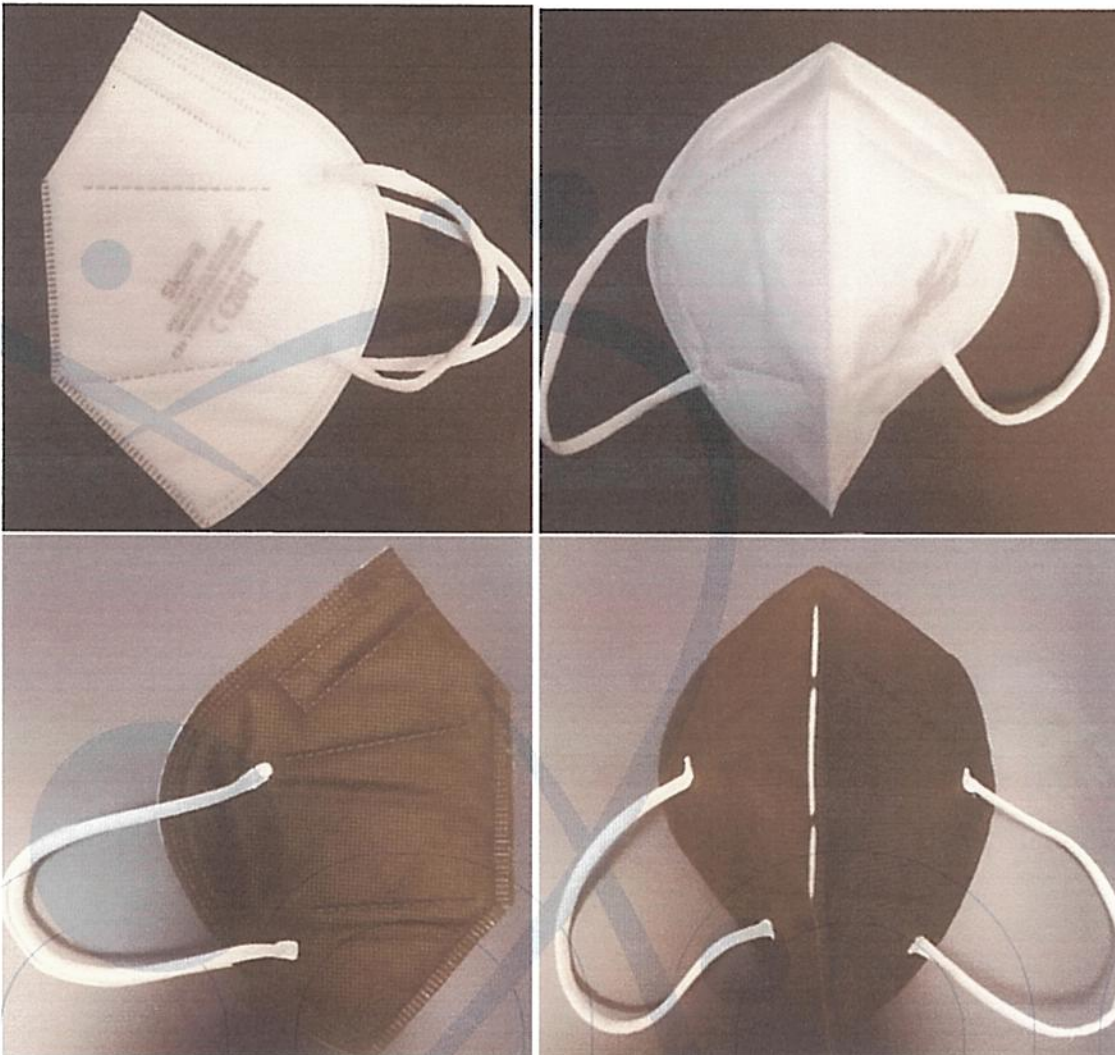
**2. PPE INFORMATION:**

Disposable and non-sterile half mask made of particulate protection filter material.

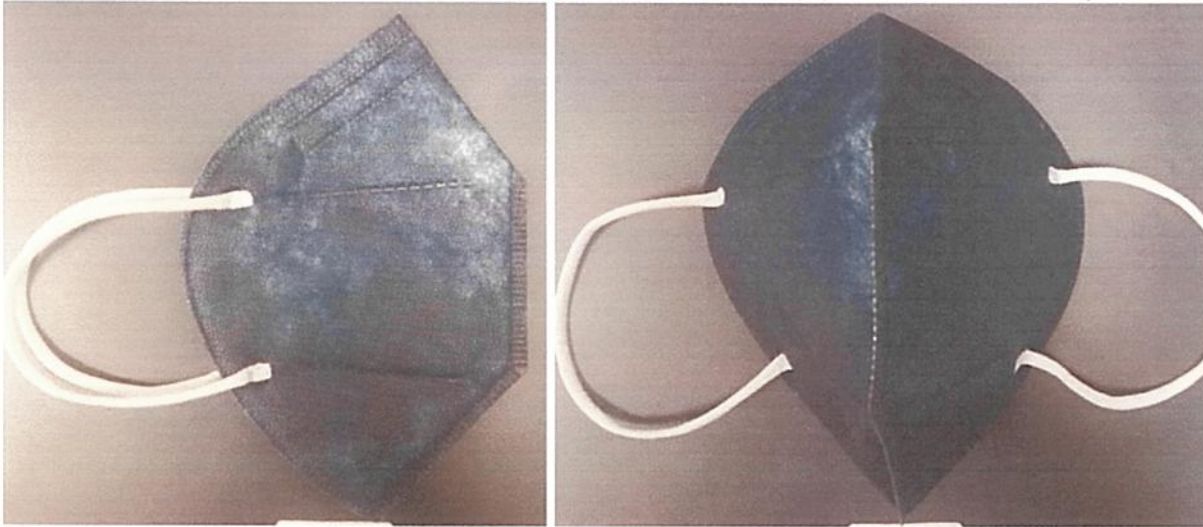
**3. PPE TYPE IDENTIFICATION**

EN 149:2001+A1:2009 Respiratory protective devices – Filtering half masks to protect against particles - Requirements, testing, marking

**4. PPE PICTURES**



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SICURA P30

**5. PPE DIMENSIONS:**

SICURA P30 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 AND EVALUATIONS:**

EN 149:2001 +A1:2009

| TESTS                      | PARAMETER   | PERFORMANCE LEVELS |      |      | RESULTS        | PERFORMANCE LEVELS | EVALUATION     |
|----------------------------|---|--------------------|------|------|----------------|--------------------|----------------|
|                            |   | FFP1               | FFP2 | FFP3 |                |                    |                |
| Banned Azo Dyes            | < 30 mg/kg  |                    |      |      | <5 mg/kg       | -                  | PASS           |
| Part 7.3 Visual inspection | Shall also the marking and the information supplied by the manufacturer   |                    |      |      | Appropriate    | -                  | PASS           |
| 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      | After cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the  |                    |      |      | Not applicable | -                  | Not applicable |

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Notified Body Number: 2841

|                                   |  |             |   |      |
|-----------------------------------|--|-------------|---|------|
| disinfecting                      | penetration requirement of the relevant class.   |             |   |      |
| 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 recieved)                     | 2.1        | 1.7        | 1.5        | 1.3        | 1.9        | 1.7     |
| Subject 2 (As recieved)                     | 1.9        | 1.6        | 1.2        | 1.0        | 1.9        | 1.5     |
| Subject 3 (As recieved)                     | 1.7        | 2.3        | 2.9        | 1.5        | 2.0        | 2.1     |
| Subject 4 (As recieved)                     | 2.2        | 1.1        | 1.9        | 1.9        | 1.5        | 1.7     |
| Subject 5 (As recieved)                     | 2.2        | 1.5        | 0.7        | 0.6        | 0.9        | 1.2     |
| Subject 6 (After temperature conditioning)  | 1.8        | 1.9        | 0.8        | 0.7        | 0.6        | 1.2     |
| Subject 7 (After temperature conditioning)  | 2.0        | 1.7        | 2.2        | 0.8        | 2.1        | 1.8     |
| Subject 8 (After temperature conditioning)  | 2.3        | 2.4        | 1.8        | 1.8        | 1.8        | 2.0     |
| Subject 9 (After temperature conditioning)  | 1.9        | 1.8        | 2.1        | 1.3        | 1.8        | 1.8     |
| Subject 10 (After temperature conditioning) | 1.0        | 0.9        | 1.9        | 1.4        | 1.9        | 1.4     |

**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               |

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

| Penetration of filter material                   | Sodium Chloride (%) | Paraffin Oil (%) |
|--|---------------------|------------------|
| As recieved                                      | 0.4                 | 0.5              |
| As recieved                                      | 0.5                 | 0.6              |
| As recieved                                      | 0.3                 | 0.6              |
| After the simulated wearing treatment            | 0.4                 | 0.5              |
| After the simulated wearing treatment            | 0.5                 | 0.7              |
| After the simulated wearing treatment            | 0.6                 | 0.6              |
| Mechanical strength and temperature conditioning | 0.8                 | 0.8              |
| Mechanical strength and temperature conditioning | 0.7                 | 0.9              |
| Mechanical strength and temperature conditioning | 0.7                 | 0.9              |

| TESTS  | PARAMETER   | PERFORMANCE LEVELS |      |      | RESULTS              | PERFORMANCE LEVELS | EVALUATION     |
|--|---|--------------------|------|------|----------------------|--------------------|----------------|
|  |   | FFP1               | FFP2 | FFP3 |                      |                    |                |
| Part 7.10<br>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<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 content of the inhalation air | Shall not exceed an average of % 1  |                    |      |      | 0,88<br>0,87<br>0,89 | -                  | 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 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<br>mbar        | 0,7<br>mbar | 1,0<br>mbar | See the table<br>below | FFP3               | PASS       |
|                                      | Inhalation 95L/min  | 2,1<br>mbar        | 2,4<br>mbar | 3,0<br>mbar | See the table<br>below | FFP3               | PASS       |
|                                      | Exhalation 160L/min | 3,0<br>mbar        | 3,0<br>mbar | 3,0<br>mbar | See the table<br>below | FFP3               | PASS       |

| Breathing Resistance (mbar)           | Inhalation 30L/min | Inhalation 95L/min |
|---------------------------------------|--------------------|--------------------|
| As recieved                           | 0.8                | 2,2                |
| As recieved                           | 0.8                | 2,2                |
| As recieved                           | 0.7                | 2,3                |
| After temperature conditioning        | 0.8                | 2,3                |
| After temperature conditioning        | 0.7                | 2,3                |
| After temperature conditioning        | 0.8                | 2,2                |
| After the simulated wearing treatment | 0.8                | 2,3                |
| After the simulated wearing treatment | 0.7                | 2,2                |
| After the simulated wearing treatment | 0.7                | 2,3                |

| 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 recieved                           | 2,8                   | 2,8                       | 2,8                         | 2,8                    | 2,7                     |
| As recieved                           | 2,8                   | 2,8                       | 2,8                         | 2,8                    | 2,8                     |
| As recieved                           | 2,7                   | 2,8                       | 2,7                         | 2,7                    | 2,7                     |
| After temperature conditioning        | 2,7                   | 2,8                       | 2,8                         | 2,8                    | 2,8                     |
| After temperature conditioning        | 2,8                   | 2,8                       | 2,8                         | 2,8                    | 2,8                     |
| After temperature conditioning        | 2,8                   | 2,8                       | 2,8                         | 2,8                    | 2,8                     |
| After the simulated wearing treatment | 2,8                   | 2,8                       | 2,8                         | 2,8                    | 2,8                     |
| After the simulated wearing treatment | 2,8                   | 2,8                       | 2,8                         | 2,8                    | 2,7                     |
| After the simulated wearing treatment | 2,8                   | 2,8                       | 2,8                         | 2,7                    | 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<br>mbar          | 5<br>mbar | 7<br>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   | 3<br>mbar          | 4<br>mbar | 5<br>mbar | Not applicable | -                  | Not applicable |

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|                            |   |  |  |                |   |  |                |
|----------------------------|---|--|--|----------------|---|--|----------------|
|                            | exhalation resistances shall not exceed. (valveless)  |  |  |                |   |  |                |
| Part 7.18 Demountable part | All demountable parts (if fitted) shall be readily connected and secured were possible by hand. |  |  | Not applicable | - |  | Not applicable |

#### 9. DECISION

Analysis and examinations SICURA P30 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-2021-00746)
- User Instruction

CONTROLLER : ERHAN ÜSTÜNEL  
SING :  
DATE : 30.04.2021

