

AB Tip İnceleme Sertifikası EU Type-Examination Certificate

Belge No / Certificate No : 33-20-02-R01
**Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /
Certification Date / Certificate Validity Date** : 17.04.2021-24.09.2025
Belge Geçerlilik Tarihi / Document Validity Period : 5 yıl / 5 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 : B MODÜLÜ/ KATEGORİ III
MODULE B / CATEGORY III
Test Rapor No/ları / Test Report No : M-2020-00286, M-2021-00644

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, kulak kayışı, burun klipsi, filtre katmanı kullanılarak imal edilmiştir./ Sicura P30V model products are manufactured using fabric, ear loop, nose clip, filter layer.

Volkan AKIN
17.04.2021
Karar Verici / Approver



Okan AKEL
17.04.2021
Şirket Müdürü / General manager





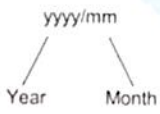

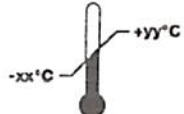

ATTACHMENTS (33-20-02-R01)

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).

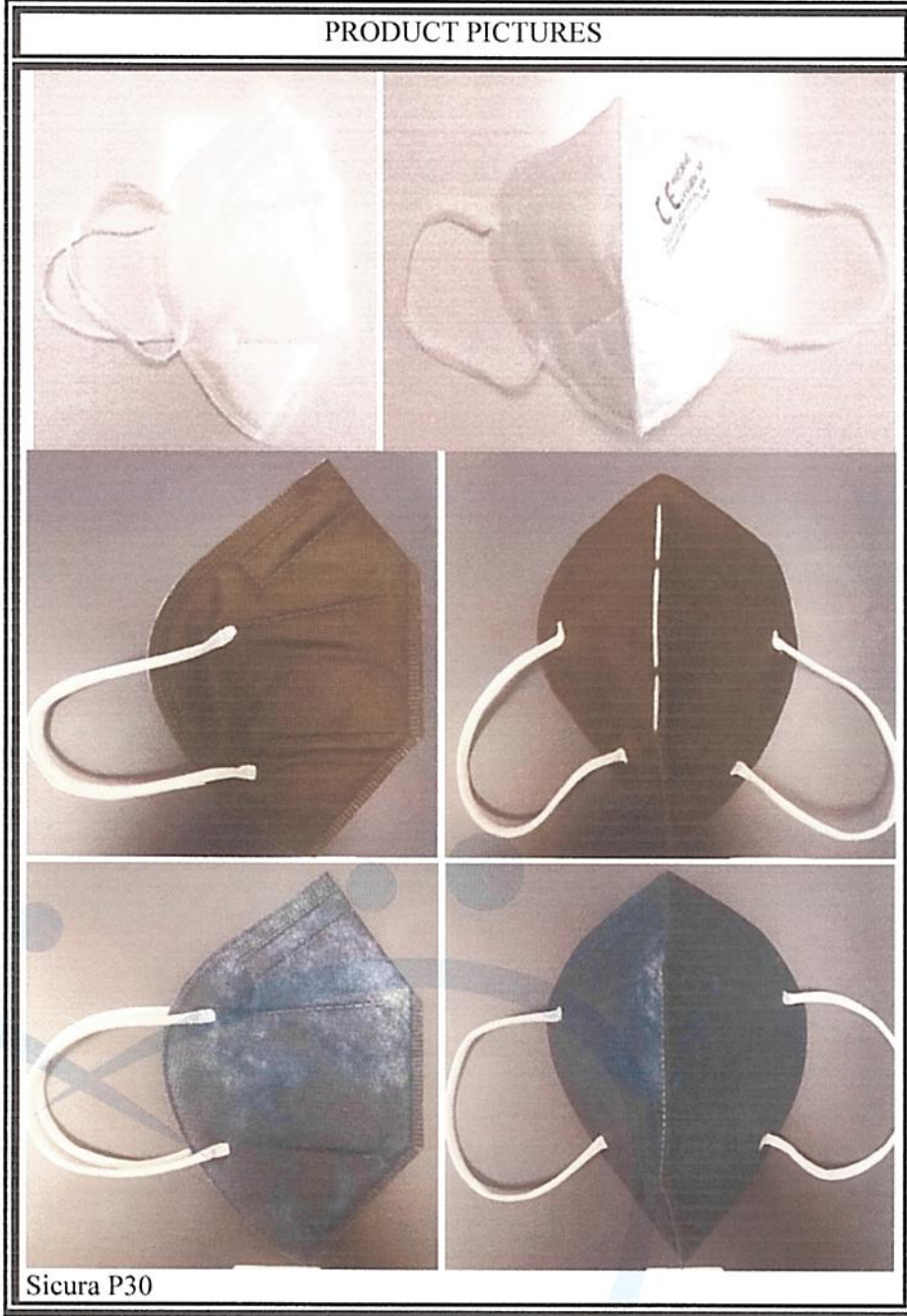
Model : Sicura P30

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					
MANUFACTURER: METALSUD LO GATTO SRL					
PPE TYPE :					
- EN 149:2001+ A1:2009 Respiratory protective devices - Filtering half masks to protect against particles					
MODEL: Sicura P30					
PICTOGRAM AND PERFORMANCE LEVELS:					
EN 149:2001+ A1:2009 FFP3 NR					
 NB 2841		 Year Month	 yyyy/mm	 -xx°C +yy°C	 < xx%
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 (33-20-02-R01)**DOCUMENTS IN THE TECHNICAL FILE**

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

Report No : 33-20-02-R01

Report Date : 17.04.2021

Application No : 33-20-02-R01

1. COMPANY INFORMATION:

METALSUD LO GATTO SRL

Zona Industriale Loc. Aeroporto 89900 Vibo Valentia (VV) ITALY

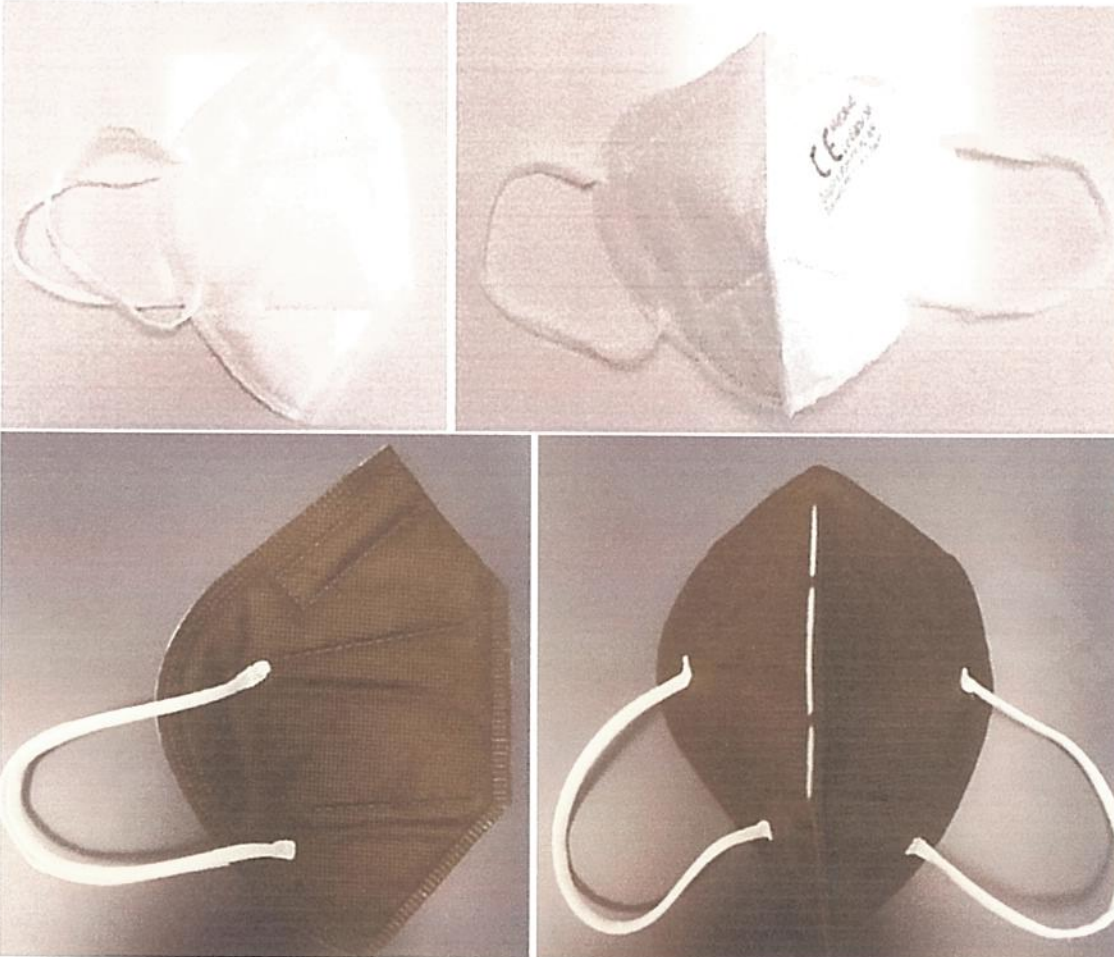
2. PPE INFORMATION:

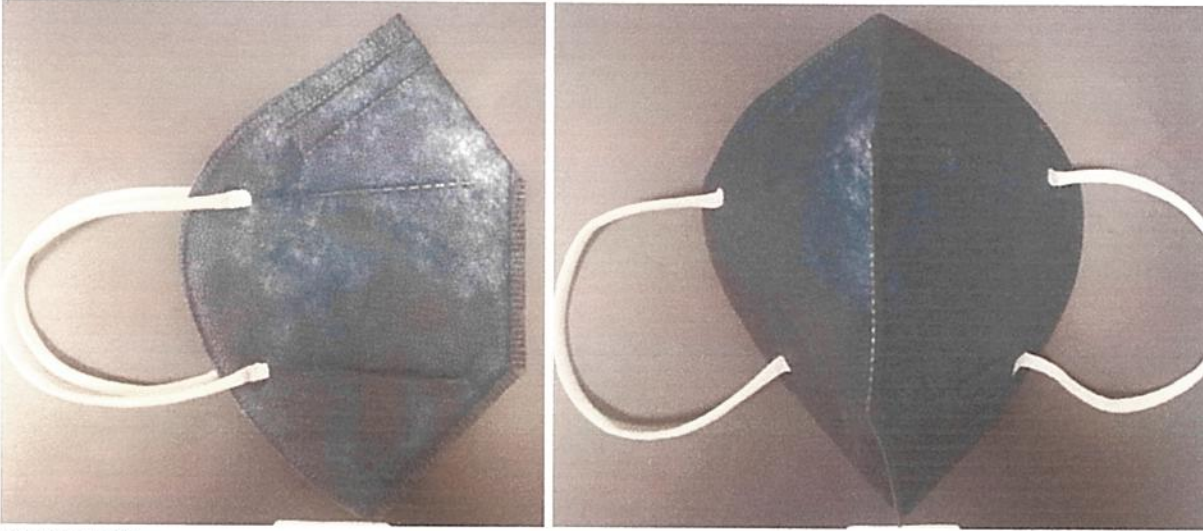
Disposable and non-sterile half mask made of particulate protection filter material.

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





SICURA P30

5. PPE DIMENSIONS:

SICURA P30 model has been found to be produced using standard 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 Visual inspection	Shall also the marking and the information supplied by the manufacturer				Appropriate	-	PASS
Banned Azo Dyes	< 30 mg/kg				<5 mg/kg	-	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 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	No negative comments should be made by				Appropriate	-	PASS

Practical performance	the test subject regarding any of the criteria evaluated.			
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	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)	2.2	1.8	1.6	1.4	2.0	1.8
Subject 2 (As recieved)	2.0	1.7	2.0	1.4	2.0	1.8
Subject 3 (As recieved)	1.8	2.4	3.0	1.6	2.1	2.2
Subject 4 (As recieved)	1.8	2.0	2.0	2.0	1.6	1.9
Subject 5 (As recieved)	2.3	1.6	1.8	1.8	2.0	1.9
Subject 6 (After temperature conditioning)	1.9	2.0	1.8	1.8	1.8	1.9
Subject 7 (After temperature conditioning)	2.1	1.8	1.9	1.9	1.8	1.9
Subject 8 (After temperature conditioning)	2.4	2.5	1.9	1.9	1.9	2.1
Subject 9 (After temperature conditioning)	2.0	1.9	2.2	1.4	1.9	1.9
Subject 10 (After temperature conditioning)	2.0	1.9	2.0	1.5	2.0	1.9

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 recieved	0.4	0.5
As recieved	0.5	0.4
As recieved	0.4	0.6
After the simulated wearing treatment	0.4	0.5
After the simulated wearing treatment	0.5	0.5
After the simulated wearing treatment	0.5	0.6
Mechanical strength and temperature conditioning	0.7	0.8
Mechanical strength and temperature conditioning	0.7	0.7
Mechanical strength and temperature conditioning	0.7	0.7

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 Carbondioxide content of the inhalation air	Shall not exceed an average of % 1				0,88 0,87 0,89	-	PASS
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. 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	FFP3	PASS
	Inhalation 95L/min	2,1 mbar	2,4 mbar	3,0 mbar			
	Exhalation 160L/min	3,0 mbar	3,0 mbar	3,0 mbar			

Breathing Resistance (mbar)	Inhalation 30L/min	Inhalation 95L/min
As recieved	0.6	2,1
As recieved	0.6	2,1
As recieved	0.6	2,1
After temperature conditioning	0.6	2,2
After temperature conditioning	0.7	2,1
After temperature conditioning	0.6	2,2
After the simulated wearing treatment	0.6	2,1
After the simulated wearing treatment	0.6	2,1
After the simulated wearing treatment	0.6	2,1
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 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
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

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. 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
- User Instruction

Reason for revision : Different color product has been added.

CONTROLLER : VOLKAN AKIN

SING :

DATE : 17.04.2021

