



C2 FFP2 NR

Documentation:

- EU Declaration of Conformity (EU - Konformitätserklärung)
- Module C2
- EU Type Examination Certificate
- Technical Evaluation Report (Test Report)
- ISO Certificates

Standards:

- EN 149 : 2001 + A1 : 2009
- Our products confirm with the 2016 / 425 EU regulation.
- ISO 9001 : 2015
- ISO 10002 : 2018
- ISO 13485 : 2016
- ISO 14001 : 2015
- ISO 45001 : 2018



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EU-KONFORMITÄT SERKLÄRUNG

HERSTELLER

AKAMED TEKSTİL MEDİKAL MALZ. VE CİHAZ SAN. DIŞ TİC. LTD.ŞTİ
Namık Kemal Mah. Sütçü İmam Cad. Tek Selvi Sk. Nr. 14 Ümraniye
İSTANBUL, TÜRKİE

PRODUKT BESCHREIBUNG

Markenname: AKA, Modell: C2
Partikelfilter-Halbmaske
Klasse: FFP2 NR

Partikelfilter-Halbgesichtsmaske in Produkt der Kategorie III gemäß (EU) 2016/425 Verordnung über persönliche Schutzausrüstung

Der Hersteller erklärt in seiner alleinigen Verantwortung, dass das oben genannte Produkt unter normalen Verwendungsbedingungen und vom Hersteller festgelegten Bedingungen sicher ist und alle erforderlichen gesetzlichen Bedingungen und Anforderungen erfüllt. Das Produkt ist eine persönliche Schutzausrüstung, die zum einmaligen Gebrauch bestimmt ist und ausschließlich den Anweisungen des Herstellers entspricht.

Die Konformität wird durch folgenden Mechanismus sichergestellt:

- Entspricht der EU-Verordnung 2016/425 über persönliche Schutzausrüstung, in der die technischen Anforderungen für Produkte der Kategorie III festgelegt sind.
- Entspricht den grundlegenden Gesundheits- und Sicherheitsanforderungen der technischen harmonisierten Norm EN 149: 2001 + A1: 2009
- Alle erforderlichen Tests gemäß den oben genannten Standards wurden durchgeführt.
- Entspricht anderen relevanten harmonisierten Gesetzen und Gemeinschaftsstandards.
- Zur Beurteilung der Konformität wird nach allen technischen Bewertungen der Konformität mit der Verordnung und den harmonisierten Normen das EU-Musterprüfzeugnis (**Seriennummer :105-20-01**) ausgestellt.

o **MNA LABORATUVARLARI SAN.TIC.LTD.ŞTİ**, als benannte **Stelle Nummer 2841**

- Das Produkt wird zur Qualitätssicherung von derselben benannten Stelle, NB 2841, gemäß Anhang III (Modul C2) der PSA-Verordnung (EU) 2016/425 überwacht.

KENNZEICHNUNG, ETIKETTIERUNG

Kennzeichnung, Kennzeichnung und Benutzerinformationen werden gemäß der EU-Verordnung über persönliche Schutzausrüstung 2016/425 und den oben angegebenen harmonisierten Produktnormen erstellt.

MASSNAHMEN ZUR SICHERHEIT DER KONFORMITÄT

Der Hersteller erklärt, dass er alle erforderlichen Maßnahmen getroffen hat, um die Konformität der in Verkehr gebrachten Produkte mit den technischen Unterlagen und technischen Anforderungen für diesen Produkttyp sicherzustellen.

ILYAS DEGERLI

General Direktor
20/12/2020

AKAMED
TEKSTİL MEDİKAL MALZ. VE CİHAZ SAN. DIŞ. TİC. LTD. ŞTİ
Namık Kemal Mah. Sütçü İmam Cad.
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ÜMRANIYE V.D.: 0120639696

CE
2841

Report No : 105-20-01-01-R01

Report Date : 02.04.2021

Application No : 105-20-01-01

1. COMPANY INFORMATION:

AKAMED TEKSTİL MEDİKAL MALZ. VE CİHAZ. SAN. DIŞ. TİC. LTD. ŞTİ.
Namık Kemal Mah. Sütçü İmam Cad. Tek Selvi Sk. No: 14 Ümraniye / İstanbul
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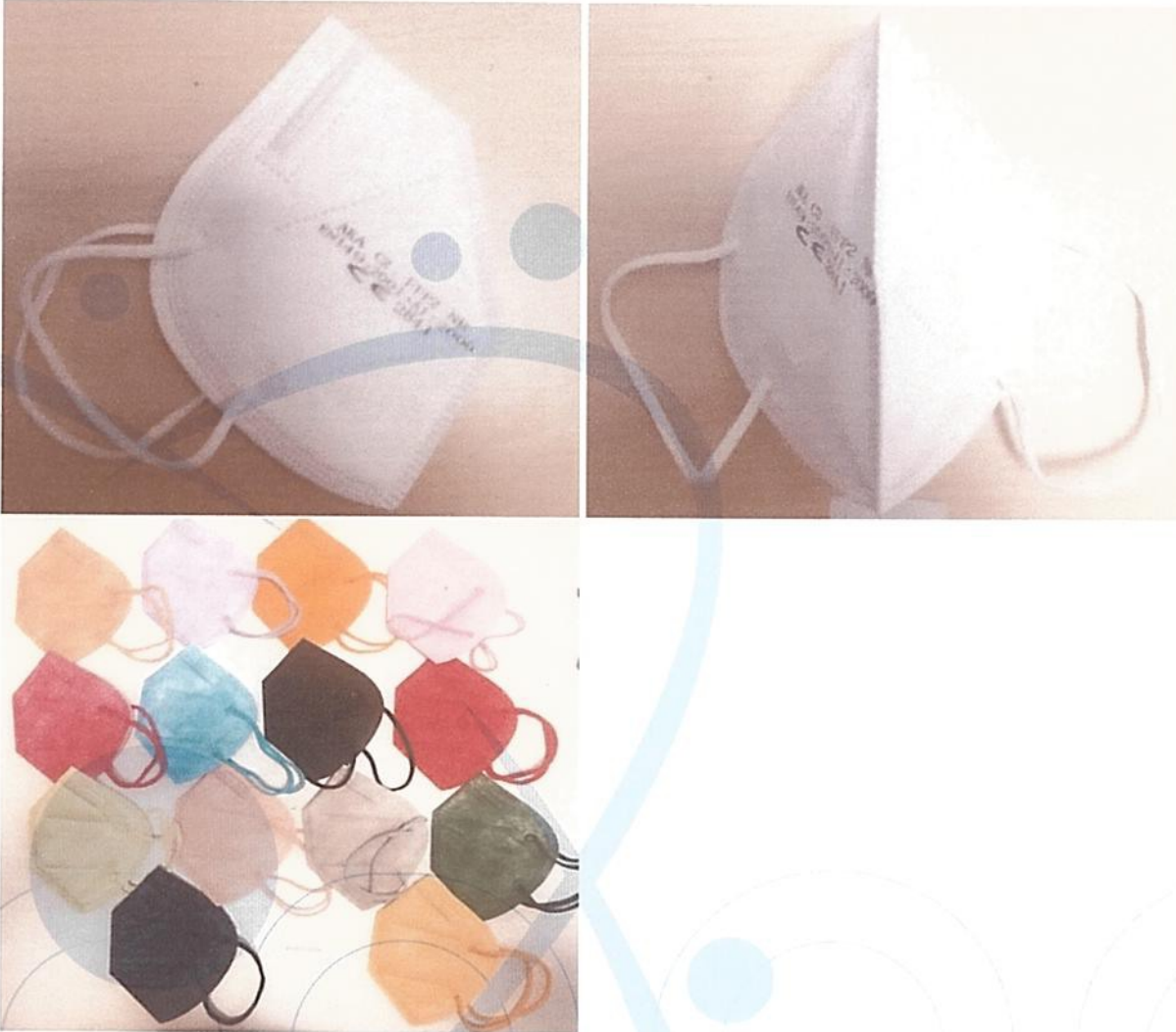
2. PPE INFORMATION:

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



AKA C2

**CONFORMITY TO TYPE BASED ON INTERNAL
PRODUCTON CONTROL PLUS SUPERVISED PRODUCT
CHECK AT RANDOM INTERVALS
(MODULE C2, ANNEX VII) (105-20-01-01-R01)**

5. PPE DIMENSIONS:

AKA C2 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 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

**CONFORMITY TO TYPE BASED ON INTERNAL
PRODUCTION CONTROL PLUS SUPERVISED PRODUCT
CHECK AT RANDOM INTERVALS
(MODULE C2, ANNEX VII) (105-20-01-01-R01)**

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 recieved)	5.2	5.5	5.4	6.0	5.3	5.5
Subject 2 (As recieved)	6.0	5.9	5.3	5.4	6.1	5.7
Subject 3 (As recieved)	5.5	5.9	5.5	5.5	5.5	5.6
Subject 4 (As recieved)	5.4	5.5	5.4	6.0	6.1	5.7
Subject 5 (As recieved)	6.0	5.3	5.5	5.6	5.5	5.6
Subject 6 (After temperature conditioning)	5.5	5.5	5.4	6.0	5.4	5.6
Subject 7 (After temperature conditioning)	6.1	5.6	5.7	6.6	6.8	6.2
Subject 8 (After temperature conditioning)	6.1	5.8	6.1	5.3	5.3	5.7
Subject 9 (After temperature conditioning)	5.5	5.4	5.5	5.2	5.5	5.4
Subject 10 (After temperature conditioning)	5.6	5.5	5.3	5.4	5.4	5.4

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

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

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Penetration of filter material	Sodium Chloride (%)	Paraffin Oil (%)
As recieved	1.9	1.8
As recieved	1.9	1.9
As recieved	2.2	2.1
After the simulated wearing treatment	2.3	2.0
After the simulated wearing treatment	2.2	2.2
After the simulated wearing treatment	2.1	2.0
Mechanical strength and temperature conditioning	1.8	2.1
Mechanical strength and temperature conditioning	1.9	1.9
Mechanical strength and temperature conditioning	2.2	1.9

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				0,60 0,67 0,63	-	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	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

**CONFORMITY TO TYPE BASED ON INTERNAL
PRODUCTON CONTROL PLUS SUPERVISED PRODUCT
CHECK AT RANDOM INTERVALS
(MODULE C2, ANNEX VII) (105-20-01-01-R01)**

Breathing Resistance (mbar)	Inhalation 30L/min	Inhalation 95L/min
As recieved	0.4	1.9
As recieved	0.4	1.8
As recieved	0.5	1.8
After temperature conditioning	0.5	1.8
After temperature conditioning	0.4	1.9
After temperature conditioning	0.5	1.8
After the simulated wearing treatment	0.5	1.9
After the simulated wearing treatment	0.5	1.8
After the simulated wearing treatment	0.4	1.9

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	1,6	1,6	1,6	1,6	1,6
As recieved	1,7	1,6	1,6	1,6	1,6
As recieved	1,6	1,6	1,6	1,6	1,6
After temperature conditioning	1,7	1,6	1,7	1,6	1,6
After temperature conditioning	1,7	1,6	1,6	1,7	1,6
After temperature conditioning	1,7	1,6	1,6	1,6	1,6
After the simulated wearing treatment	1,7	1,7	1,7	1,6	1,6
After the simulated wearing treatment	1,6	1,6	1,7	1,7	1,7
After the simulated wearing treatment	1,6	1,6	1,6	1,6	1,6

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

**CONFORMITY TO TYPE BASED ON INTERNAL
PRODUCTION CONTROL PLUS SUPERVISED PRODUCT
CHECK AT RANDOM INTERVALS
(MODULE C2, ANNEX VII) (105-20-01-01-R01)**

9. DECISION

Analysis and examinations AKA C2 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-2020-00722, M-2021-00448)
- User Instruction

Reason for revision : Different color product has been added.

CONTROLLER : ERHAN ÜSTÜNEL

SING :

DATE : 02.04.2021

EU-Baumusterprüfbescheinigung EU Type-Examination Certificate

Zertifikat Nr. / Certificate No : 105-20-01
Zertifizierungsdatum - Gültigkeitsdatum des Zertifikats/
Certification Date- Certificate Validity Date : 20.12.2020-20.12.2025
Gültigkeitsdauer des Dokuments/ Document Validity Period : 5 Jahre / 5 years
Firmenname und Adresse/
Company Name and Address : AKAMED TEKSTİL MEDİKAL MALZ. VE CİHAZ
SAN. DIŞ. TİC. LTD. ŞTİ.
Namık Kemal Mah. Sütçü İmam Cad. Tek Selvi Sk. No:
14 Ümraniye / İstanbul
Produktname / Modelle/ Product Name / Models : AKA C2
Richtlinie/ Directive : EU 2016/425 VERORDNUNG/REGULATION
Modul / Kategorie/ Module / Category : B Modul / Kategorie III
MODULE B / CATEGORY III
Prüfbericht Nr. / Test Report No : MNA M-2020-00602
Produkttyp / Product Type:
- EN 149:2001+ A1:2009 Atemschutzgeräte. Filtrierende Halbmasken zum Schutz gegen Partikeln.
Anforderungen, Prüfung, Kennzeichnung/ Respiratory protective devices - Filtering half masks to protect
against particles

Produktmaterial Informationen / Product Material Information: Die Produkte des AKA C2 modells werden aus stoff, ohrschlaufe, nasenclip und filterschicht hergestellt.. / AKA C2 model products are manufactured using fabric, ear loop, nose clip, filter layer.

Volkan AKIN
04.01.2021

Genehmiger / Approver



Okan AKEL
04.01.2021

Generaldirektor / General manager



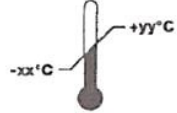
ANHÄNGE (105-20-01)

Zur Zertifizierung des PSA-Produkts auf Stufe III wird das Modul C2 oder D von der Anwendung einer der Konformitätsbewertungsmethoden zusammen mit der EU-Typprüfung (Modul B) begleitet.

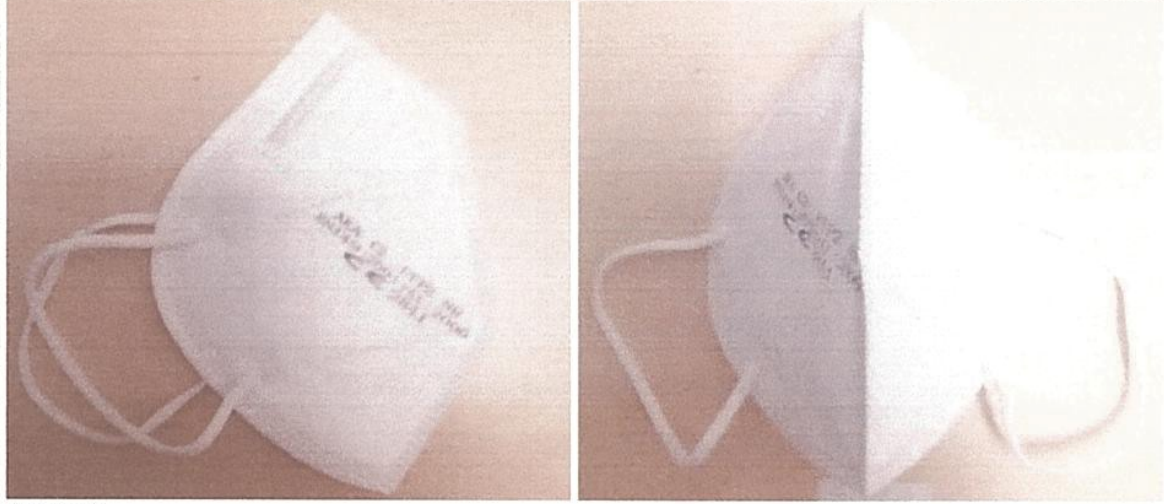
Modell : AKA C2

PSA-SPEZIFIKATION	LEISTUNGSSTUFEN
Einstufung	FFP2
Wiederverwendbare / Single-Shift-Verwendung	NR

PSA, die als einzelne Einheit für einen einzelnen Benutzer hergestellt wird, alle erforderlichen Anweisungen zur Herstellung dieser PSA auf der Grundlage des genehmigten Grundmodells:

MARKIERUNG	
HERSTELLER: AKAMED TEKSTİL MEDİKAL MALZ. VE CİHAZ. SAN. DIŞ. TİC. LTD. ŞTİ.	
PSA TYP : - EN 149:2001+ A1:2009 Atemschutzgeräte. Filtrierende Halbmasken zum Schutz gegen Partikeln. Anforderungen, Prüfung, Kennzeichnung	
MODELL: AKA C2	
PICTOGRAMM- UND LEISTUNGSSTUFEN:	
EN 149:2001+ A1:2009 FFP2 NR	
 NB 2841	 Year Month yyyy/mm
 yyyy/mm	 -xx°C +yy°C
 < xx% Lagerungszustand	

MNA LABORATORIES SAN. TIC. LTD. ŞTİ erklärt, dass das oben genannte Produkt die Anforderungen der Richtlinie gemäß der EU-Richtlinie 2016/425 erfüllt. Die Sicherheit des Produkts wird durch die Bedingungen und die Verwendung abgedeckt, die in diesem Zertifikat und in der technischen Datei angegeben sind.

ANHÄNGE (105-20-01)**PRODUKTBILDER**

AKA C2

DOKUMENTE IN DER TECHNIK

- Grundlegende Anforderungen an die Gesundheitssicherheit
- Risikoabschätzung
- Testberichte
- Technischer Bericht

AB Tip İnceleme Sertifikası EU Type-Examination Certificate

Belge No / Certificate No : 105-20-01
Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /
Certification Date / Certificate Validity Date : 20.12.2020-20.12.2025
Belge Geçerlilik Tarihi / Document Validity Period : 5 yıl / 5 years
Firma Unvanı ve Adresi /
Company Name and Address : AKAMED TEKSTİL MEDİKAL MALZ. VE
CİHAZ. SAN. DİŞ. TİC. LTD. ŞTİ.
Namık Kemal Mah. Sütçü İmam Cad. Tek Selvi Sk.
No: 14 Ümraniye / İstanbul

Ürün Adı /Modeller / Product Name / Models : AKA C2
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-2020-00602
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: AKA C2 model ürünleri kumaş, kulak kayışı, burun klipsi ve filtre katmanını kullanılarak imal edilmiştir./ AKA C2 model products are manufactured using fabric, ear loop, nose clip, filter layer.

Volkan AKIN
20.12.2020
Karar Verici / Approver



Okan AKEL
20.12.2020
Şirket Müdürü / General manager



MNA Laboratuvarları San. Tic.Ltd .Şti
Adres: Küçükbakkalköy Mahallesi Yenidoğan Cad.No:21 Ataşehir/ İstanbul
Tel: 0216 574 07 08 Faks: 0216 575 13 31 www.mnalab.com

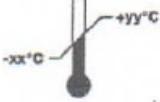
ATTACHMENTS (105-20-01)

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).

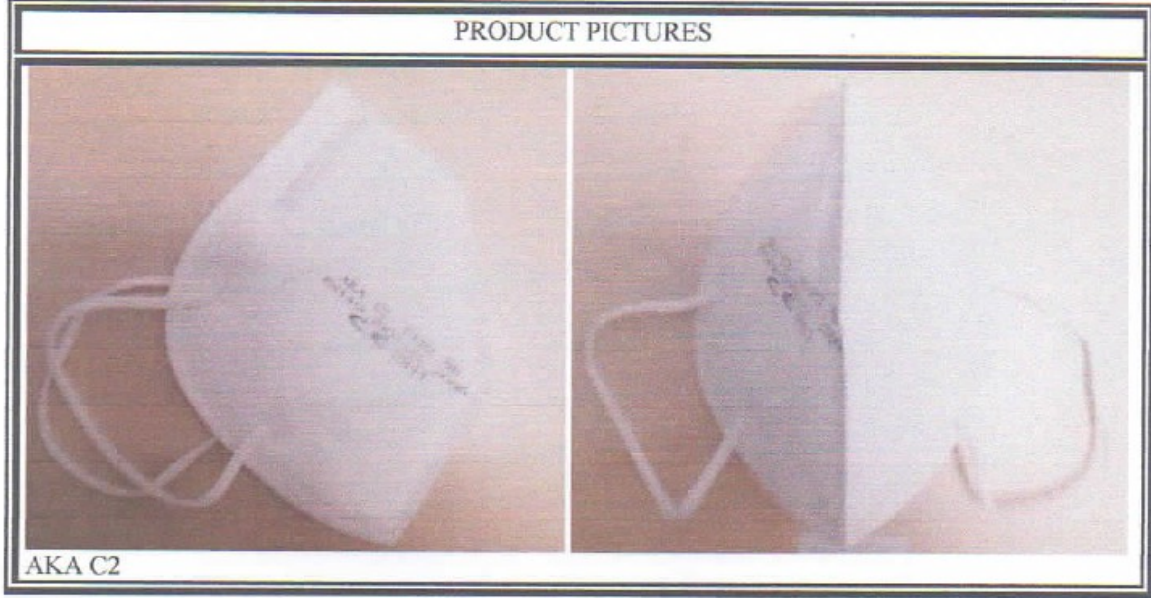
Model : AKA C2

PPE SPECIFICATION	PERFORMANCE LEVELS
Classification	FFP2
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: AKAMED TEKSTİL MEDİKAL MALZ. VE CİHAZ. SAN. DIŞ. TİC. LTD. ŞTİ.	
PPE TYPE :	
- EN 149:2001+ A1:2009 Respiratory protective devices - Filtering half masks to protect against particles	
MODEL: AKA C2	
PICTOGRAM AND PERFORMANCE LEVELS:	
EN 149:2001+ A1:2009 FFP2 NR	
 NB 2841	 Year Month yyyy/mm
 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 (105-20-01)**DOCUMENTS IN THE TECHNICAL**

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

 MNA LABORATUVARLARI SAN. TİC. LTD. ŞTİ.	MNA LABORATUVARLARI TECHNICAL EVALUATION REPORT (105-20-01)
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Report No :105-20-01
Report Date :20.12.2020
Application No :105-20-01

1. COMPANY INFORMATION:

AKAMED TEKSTİL MEDİKAL MALZ. VE CİHAZ. SAN. DİŞ. TİC. LTD. ŞTİ.
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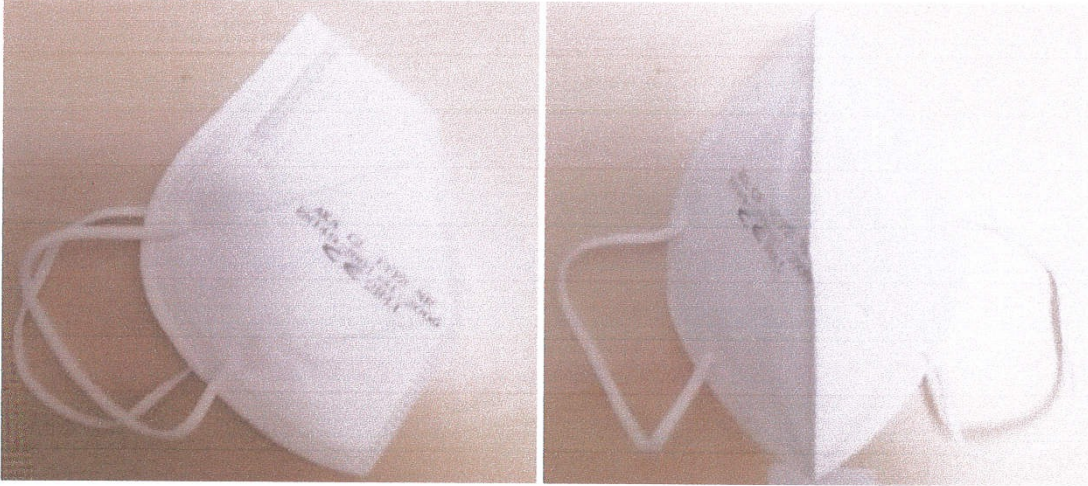
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4. PPE PICTURES



AKA C2

5. PPE DIMENSIONS:

AKA C2 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, 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.
- Respiratory protective dimensions are evaluated according to EN 149:2001 +A1:2009.
- Conditioning EN 149:2001 +A1:2009 part 8.3, Penetration EN 149:2001 +A1:2009 part 8.11 (EN 13274-7), Application performance EN 149:2001 +A1:2009 part 8.4, Inward leakage EN 149:2001 +A1:2009 part 8.5, Flammability EN 149:2001 +A1:2009 part 8.6, The carbon dioxide content of the inhaled air EN 149:2001 +A1:2009 part 8.7, Inhalation resistance EN 149:2001 +A1:2009 part 8.9, Exhalation resistance EN 149:2001 +A1:2009 part 8.9 has been tested and evaluated.

8. ANALYSIS AND EVALUATIONS:

EN 149:2001 +A1:2009

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Visual inspection	Shall also the marking and the information supplied by the manufacturer				Appropriate	-	PASS
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
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Subject 10 (After temperature conditioning)	5.6	5.5	5.3	5.4	5.4	5.4



MNA LABORATUVARLARI SAN. TİC. LTD. ŞTİ.

MNA LABORATUVARLARI

TECHNICAL EVALUATION REPORT (105-20-01)

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Flammibility	Mask shall not burn or not to continue to burn for more than 5 s				Flame not seen	-	PASS
Carbondioxide content of the inhalation air	Shall not exceed an average of % 1				0.60 0.67 0.63	-	PASS
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 recieved	2.2	2.4
As recieved	2.5	3.4
As recieved	3.2	1.6
After the simulated wearing treatment	3.2	2.2
After the simulated wearing treatment	2.6	2.4
After the simulated wearing treatment	3.3	2.7
Mechanical strength and temperature conditioning	3.5	3.3
Mechanical strength and temperature conditioning	3.6	3.2
Mechanical strength and temperature conditioning	3.6	2.6

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Compatibility with skin	Materials shall not be known to be likely to cause irritation or any other adverse effect to health				Appropriate	-	PASS
Head harness	It can be donned and removed easily				Appropriate	-	PASS
Breathing Resistance	Inhalation 30L/min	0,6 mbar	0,7 mbar	1 mbar	See the table below	FFP2	PASS
	Inhalation 95L/min	2,1 mbar	2,4 mbar	3 mbar	See the table below	FFP2	PASS
	Exhalation 160L/min	3 mbar	3 mbar	3 mbar	See the table below	FFP2	PASS

Breathing Resistance (mbar)	Inhalation 30L/min	Inhalation 95L/min
As recieved	0.4	1.9
As recieved	0.4	1.8
As recieved	0.5	1.8



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TECHNICAL EVALUATION REPORT (105-20-01)

After temperature conditioning	0.5	1.8
After temperature conditioning	0.4	1.9
After temperature conditioning	0.5	1.8
After the simulated wearing treatment	0.5	1.9
After the simulated wearing treatment	0.5	1.8
After the simulated wearing treatment	0.4	1.9

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	1,6	1,6	1,6	1,6	1,6
As recieved	1,7	1,6	1,6	1,6	1,6
As recieved	1,6	1,6	1,6	1,6	1,6
After temperature conditioning	1,7	1,6	1,7	1,6	1,6
After temperature conditioning	1,7	1,6	1,6	1,7	1,6
After temperature conditioning	1,7	1,6	1,6	1,6	1,6
After the simulated wearing treatment	1,7	1,7	1,7	1,6	1,6
After the simulated wearing treatment	1,6	1,6	1,7	1,7	1,7
After the simulated wearing treatment	1,6	1,6	1,6	1,6	1,6

9. DECISION PROPOSAL

Analysis and examinations AKA C2 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 Reports
- User Instruction

CONTROLLER : VOLKAN AKIN

SING :

DATE : 20.12.2020



Sertifika

ISO 9001 : 2015

**AKAMED TEKSTİL MEDİKAL MALZ.
VE CİHAZ. SAN. DIŞ. TİC. LTD. ŞTİ.**

Namık Kemal Mah. Tek Selvi Sk. Moss Apt. No: 14 Ümraniye/ İstanbul/TÜRKİYE

Bu sertifika yukarıdaki kuruluşa ait kalite yönetim sisteminin aşağıdaki kapsam çerçevesinde PCA Sertifikasyon tarafından onaylandığını göstermekte olup, sertifikanın geçerliliği kuruluşun yıllık gözetim denetimlerinden geçmesine ve Uluslararası akreditasyon kuralları gereğince ilgili yönetim sisteminin şartlarını devam ettirmesine bağlıdır.

KAPSAM

Tek kullanımlık tıbbi yüz maskesi, partikül filtreli yarım maske ile tulum ve önlük üretimi, satışı, ithalatı ve ihracatı

EA KODU
04 - 29

Sertifika No : KY-27255
Tescil Tarihi : 16.10.2020
Yeniden Basım Tarihi :
Geçerlilik Tarihi : 15.10.2021
Belge Periyodu : 3 Yıl (Tescil Tarihinden itibaren)
Hariç Tutma : 8.3



PCA Sertifikasyon Onayı

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FR-86 Rev-4



Sertifika

ISO 10002 : 2018

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VE CİHAZ. SAN. DIŞ. TİC. LTD. ŞTİ.**

Namık Kemal Mah. Tek Selvi Sk. Moss Apt. No: 14 Ümraniye/ İstanbul/TÜRKİYE

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KAPSAM

Tek kullanımlık tıbbi yüz maskesi, partikül filtreli yarım maske ile tulum ve önlük üretimi, satışı, ithalatı ve ihracatı

Sertifika No : MM-70521
Tescil Tarihi : 16.10.2020
Yeniden Basım Tarihi :
Geçerlilik Tarihi : 15.10.2021
Belge Periyodu : 3 Yıl (Tescil Tarihinden itibaren)



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CERTIFICATE OF REGISTRATION



*This is to Certify that the
Medical Devices - Quality Management System
of*

AKAMED TEKSTİL MEDİKAL MALZEME VE CİHAZLAR SANAYİ DİŞ TİCARET LİMİTED ŞİRKETİ

NAMIK KEMAL MAH. TEK SELVİ SOK. MOSS APT. NO:14
ÜMRANIYE / İSTANBUL / TÜRKİYE

has been independently assessed and is compliant
with the requirements of

ISO 13485:2016

This Certificate is applicable to the following product or service ranges:

PRODUCTION, SALES, IMPORT AND EXPORT OF DISPOSABLE MEDICAL FACE MASK,
PARTICLE FILTERED HALF MASK WITH OVERALLS AND GOWN

TEK KULLANIMLIK TIBBİ YÜZ MASKESİ, PARTİKÜL FİLTRELİ YARIM MASKE İLE
TULUM VE ÖNLÜK ÜRETİMİ, SATIŞI, İTHALATI VE İHRACATI

Certificate No.: TR53349H

Date of initial registration	14 October 2020
Date of this Certificate	14 October 2020
Surveillance audit on or before	13 October 2021
Recertification Due / Certificate expiry	13 October 2023



This Certificate is remains valid subject to satisfactory surveillance audits.

Emmanuel

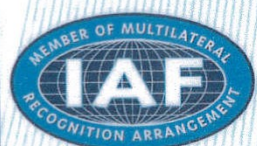
Emmanuel ADEMOSU
Director

For verification and updated information concerning the present certificate visit to http://staunchlyservices.com/search_certified_client.php
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STAUNCHLY MANAGEMENT AND SYSTEM SERVICES LIMITED

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Great Manchester, England-SK1 3DG
Web :- www.staunchlyservices.com
E-mail :- info@staunchlyservices.com
Phone :- +44 740 482 3687

Company Registered in England and Wales with Company Number 11488683





Sertifika

ISO 14001 : 2015

**AKAMED TEKSTİL MEDİKAL MALZ.
VE CİHAZ. SAN. DIŞ. TİC. LTD. ŞTİ.**

Namık Kemal Mah. Tek Selvi Sk. Moss Apt. No: 14 Ümraniye/ İstanbul/TÜRKİYE

Bu sertifika yukarıdaki kuruluşa ait çevre yönetim sisteminin aşağıdaki kapsam çerçevesinde PCA Sertifikasyon tarafından onaylandığını göstermekte olup, sertifikanın geçerliliği kuruluşun yıllık gözetim denetimlerinden geçmesine ve Uluslararası akreditasyon kuralları gereğince ilgili yönetim sisteminin şartlarını devam ettirmesine bağlıdır.

KAPSAM

Tek kullanımlık tıbbi yüz maskesi, partikül filtreli yarım maske ile tulum ve önlük üretimi, satışı, ithalatı ve ihracatı

EA KODU

04 - 29

Sertifika No : CY-33246
Tescil Tarihi : 16.10.2020
Yeniden Basım Tarihi :
Geçerlilik Tarihi : 15.10.2021
Belge Periyodu : 3 Yıl (Tescil Tarihinden itibaren)



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Sertifika

ISO 45001 : 2018

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Namık Kemal Mah. Tek Selvi Sk. Moss Apt. No: 14 Ümraniye/ İstanbul/TÜRKİYE

Bu sertifika yukarıdaki kuruluşa ait iş sağlığı ve güvenliği yönetim sisteminin aşağıdaki kapsam çerçevesinde PCA Sertifikasyon tarafından onaylandığını göstermek için ekte olup, sertifikanın geçerliliği kuruluşun yıllık gözetim denetimlerinden geçmesine ve Uluslararası akreditasyon kuralları gereğince ilgili yönetim sisteminin şartlarını devam ettirmesine bağlıdır.

KAPSAM

Tek kullanımlık tıbbi yüz maskesi, partikül filtreli yarım maske ile tulum ve önlük üretimi, satışı, ithalatı ve ihracatı

Sertifika No : OH-52829
Tescil Tarihi : 16.10.2020
Yeniden Basım Tarihi :
Geçerlilik Tarihi : 15.10.2021
Belge Periyodu : 3 Yıl (Tescil Tarihinden itibaren)



PCA Sertifikasyon Onayı

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