aka

MASK

C2 FFP2 NR

Documentation:

- Technical Sheet and Dimension Information
- 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

Automatisch absorbierender Filtertyp Anti-Fog / Automatic Absorbing Filter Type Anti-Fog | Verbesserte Atemschutzmaske / Enhanced Respirator

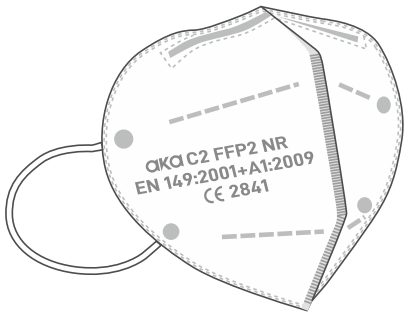
AKA C2 FFP2 NR

aka MASK

Atemschutzmasken-Gebrauchsanweisung
Half Mask User Instruction

SCHUTZMASKE
PROTECTIVE MASK
FFP2 NR
EN149:2001+A1:2009

MASK / MASQUE / MASKE / MASKEER
MASCHERE / MASCARA / MASCARAR



- Hohe Filtrationseffizienz
- Niedriger Atemwiderstand
- Bequem zu tragen

- More Comfortable to Wear
- Low Respiratory Resistance
- High Filtration Efficiency

SO TRAGEN SIE IHRE MASKE

Platzieren Sie Ihre Maske 1
Legen Sie die Maske mit der Innenfläche nach oben auf. Legen Sie sie auf ihr Kinn und über Ihre Nase.

Anlegen der Ohrbänder 2
Legen Sie die Ohrbänder nach eigenem Ermessen rechts und links über beide Ohren.

Einstellen des Nasenbügels 3
Passen Sie den Nasenbügel mit beiden Händen varsichtig an Ihre Nase an.

Sitz prüfen 4
Vergewissern Sie sich, dass die Maske Ihre Nase, Ihren Mund und Ihr Kinn vollständig bedeckt und gut sitzt.

HOW TO WEAR YOUR MASK

Place your mask 1
Place the mask with the inner surface facing up. Place it on your chin and over your nose.

Put on ear bands 2
Put the ear bands right & left over both ears at your own discretion

Adjust the nose clip 3
Use both hands to carefully adjust the nose piece to your nose.

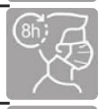
Check fit 4
Make sure the mask completely covers your nose, mouth & chin & fits snugly.

GEBRAUCHSANWEISUNG

1 **Nicht berühren**
Berühren Sie die Maske nicht, wenn Infektionsrisiko besteht. Setzen Sie in diesem Fall sofort eine neue Maske auf.

2 **Maske austauschen**
Sollten Sie Nässe und Feuchtigkeit innerhalb oder außerhalb der Maske spüren, setzen Sie bitte sofort eine neue Maske auf.

3 **Maximale Tragezeit**
Die maximale Zeit, in der Sie Ihre Maske tragen können, beträgt 8 Stunden. Bitte überschreiten Sie die maximale Tragezeit nicht.



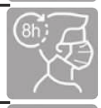
4 **Abnehmen**
Nehmen Sie die Maske nur ab, indem Sie die Ohrbügeln nach unten ziehen

USER INSTRUCTIONS

1 **Do not touch**
Do not touch the mask outside in the danger area. In this case, immediately put on a new mask.

2 **Exchange your mas**
In case of feeling wetness and humidity either inside or outside of your mask, please put on. a new mask immediately.

3 **Maximum wearing time**
The maximum time that you can wear your mask for one time is 8 hours. Please do not exceed maximum using time.



4 **Taking the mask off**
Take off the mask only by pulling down the ear straps.

HIGH EFFICIENCY FILTRATION

COMFORTABLE LAMINATING

HEALTHY BREATHING

4-LAYER OF PROTECTION

Model No
AKA C2

Hinweis:

Diese Masken sollten NICHT getragen werden, von Kindern unter 2 Jahren, von Personen die Schwierigkeiten beim Atmen haben und von Personen die handlungsunfähig oder nicht in der Lage sind, diese Masken ohne Hilfe wieder abzunehmen.

Die Maske muss sofort gewechselt werden, wenn es beschädigt ist oder nass wird.

Verwenden Sie die Maske nicht wieder. Es wird empfohlen, die maximale Anwendungsdauer von 8 Stunden nicht zu überschreiten. Waschen, desinzifizieren oder erhitzen Sie die Maske nicht.

Personen, die gegen Polypropolen allergisch sind, dürfen diese Maske nicht verwenden.

Note:

Masks should NOT be worn by children under the age of 2 or anyone who has trouble breathing, is unconscious, incapacitated, or otherwise unable to remove the mask without assistance.

This mask must be immediately changed when it is damaged or wet.

This mask is just for single use.

Do not reuse the mask. We recommend the maximum application time of 8 hours not to be exceeded. Do not wash, disinfect, or heat the mask.

People who are allergic to polypropolene must not use this mask.

Sicherheitsausrüstung

- Kontrollieren Sie die Maske, bevor Sie in den Anwendungsbereich eintreten.
- Im Arbeitsbereich muss mindestens 19,5% Vol. Sauerstoff vorhanden sein. Anderenfalls kann die Maske nicht verwendet werden.
- Die Masken schützen Sie vor Gas und Dampf nicht.
- Wechseln Sie die Maske, wenn der Atemwiederstand ansteigt.
- Wiederholen Sie den Vorgang 1-2-3-4 im Falle einer Undichtigkeit.

Safety Equipment

- Control the mask before get in the using area.
- In working area there must be at least %19,5 oxygen otherwise mask not able to use.
- The masks do not protect you from gases and steam
- Change the mask if there will be any obvious and realizable extra air resisting.
- If there is any leakage redo the 1-2-3-4 process again.

Notifizierter Körper/Notified Body
MNA Laboratuvarları San. Tic. Ltd. Şti. NB2841

Turkey
Discover the potential

CE 2841

Zertifikate / Certificates

Kontakt / Contact

ISO 9001 COMPANY | ISO 10002 COMPANY | ISO 45001 COMPANY | ISO 13485 COMPANY | ISO 14001 COMPANY

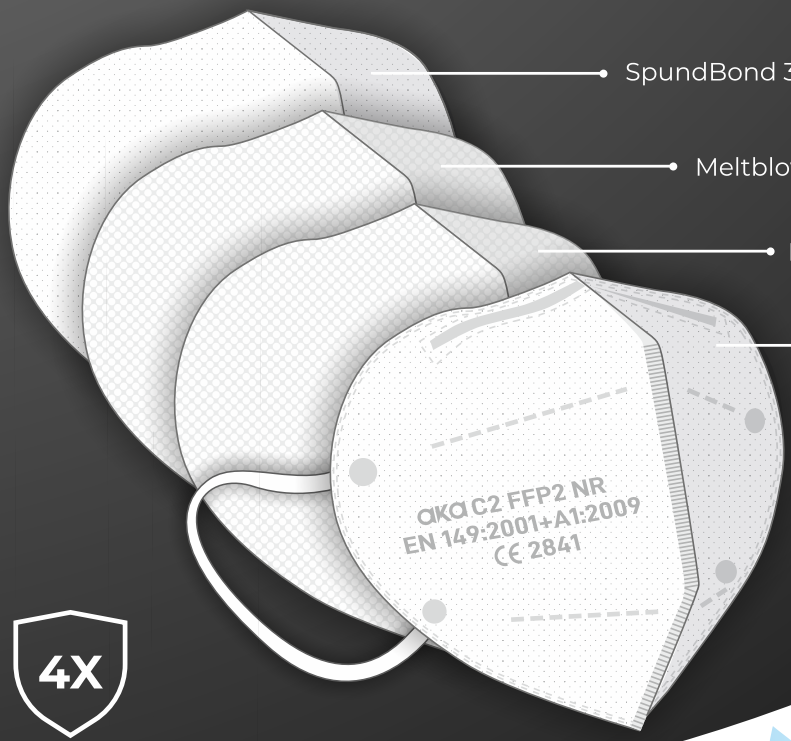
Manufacturer
aka MASK

Akamed Tekstil Medikal Malzemeleri ve Cihaz San. Dış Tic. Ltd. Şti.
Namık Kemal Mah Sütçü İmam Cad. Tek Selvi Sk.
No : 14 Ümraniye - İstanbul
+90 216 532 00 94 - info@akamask.com - www.akamask.com

Deutschland Distributor :
Grosshandel Hoffmann GmbH & Co.KG -
Augustastrasse 6b 47441 Moers / Deutschland
+49 2841 3675668 - info@aka-mask.de - www.aka-mask.de

C2 FFP2 NR

aka MASK



4X
PROTECTIVE LAYERS

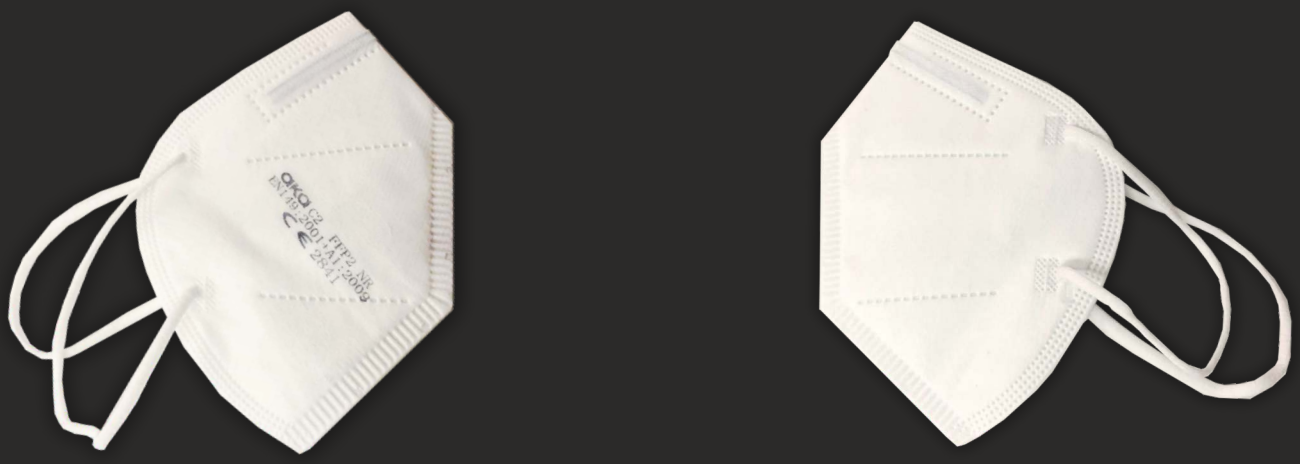
- Hohe Filtrationseffizienz
- Niedriger Atemwiderstand
- Bequem zu tragen

- More Comfortable to Wear
- Low Respiratory Resistance
- High Filtration Efficiency

PROTECTIVE MASK
SCHUTZMASKE
FFP2 NR
EN149:2001+A1:2009

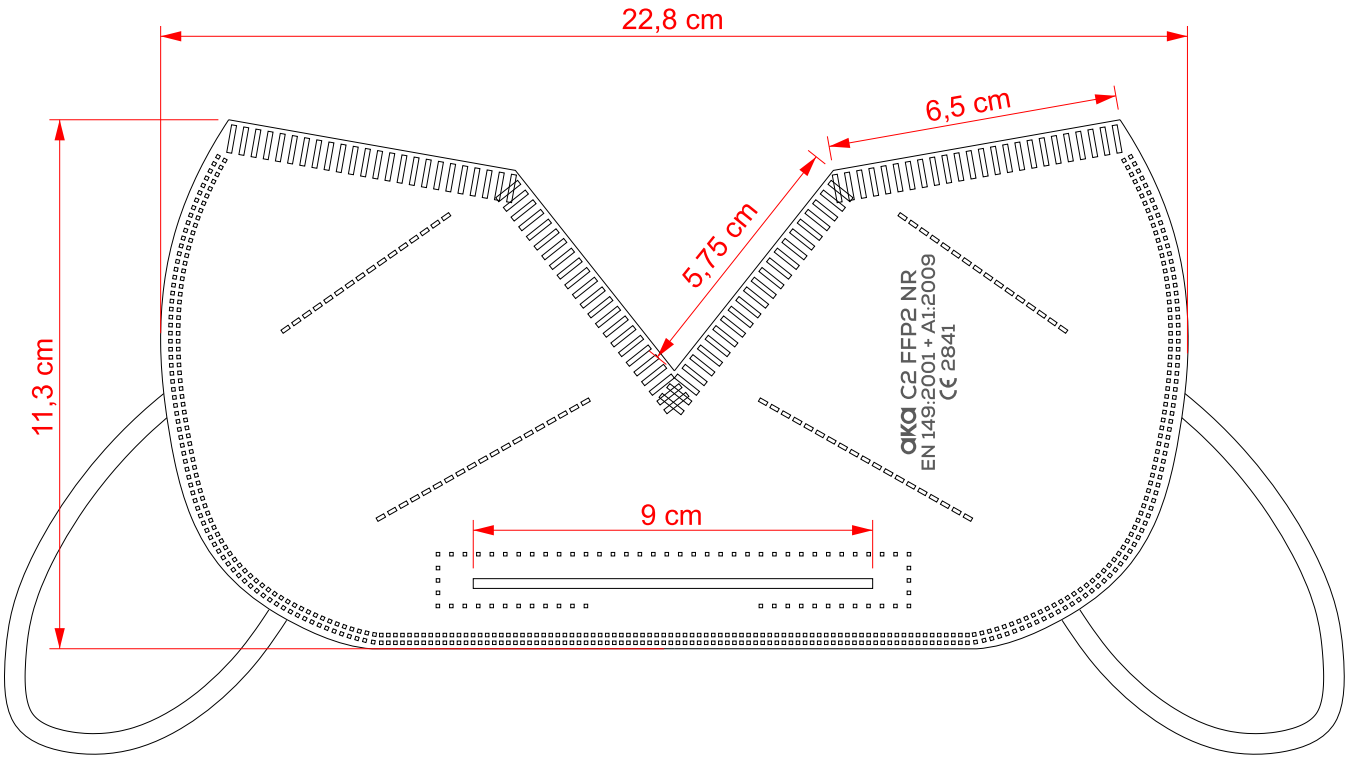
MASK / MASQUE / MASKE / MASKEER
MASCHERE / MASCARA / MASCARAR

HIGH EFFICIENCY FILTRATION | COMFORTABLE LAMINATING | HEALTHY BREATHING | 4-LAYER OF PROTECTION



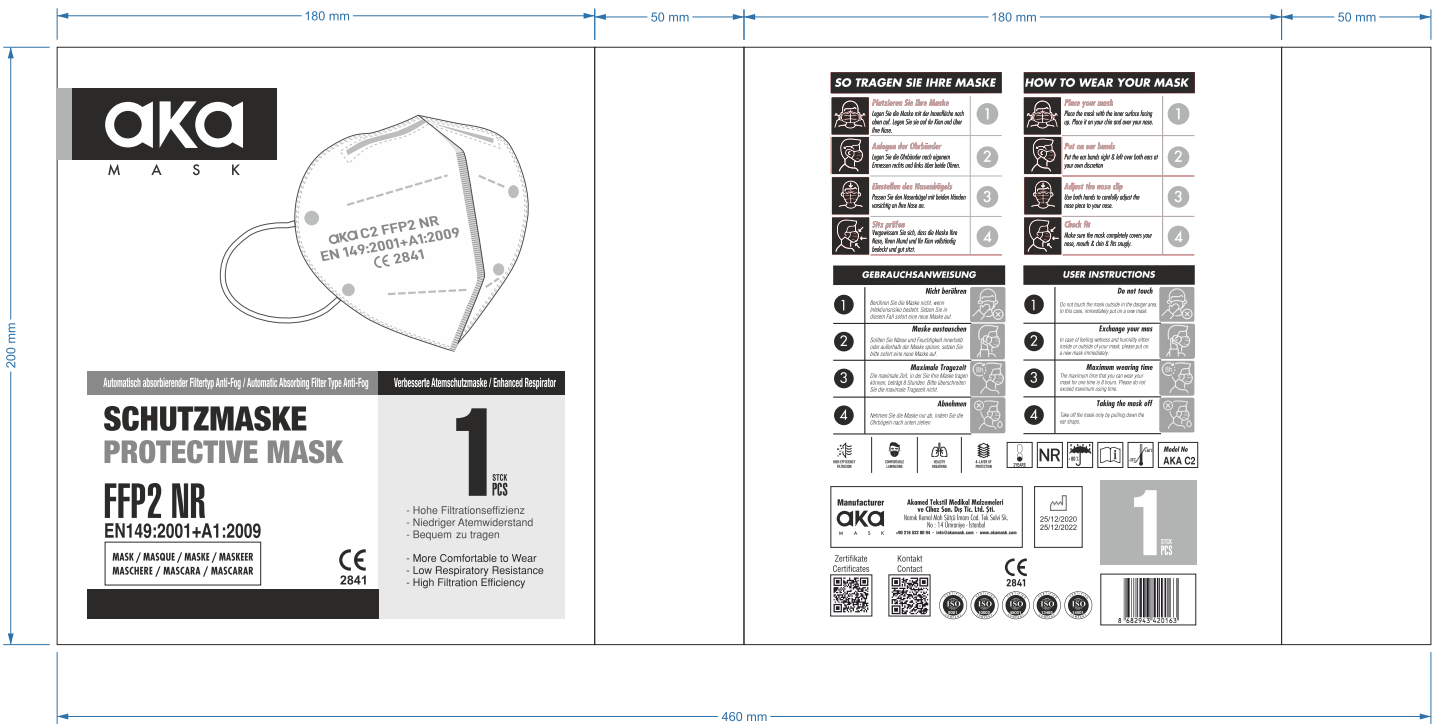
CE 2841 EN 149 : 2001 + A1 : 2009

C2 FFP2 NR



CE 2841 EN 149 : 2001 + A1 : 2009

C2 FFP2 NR

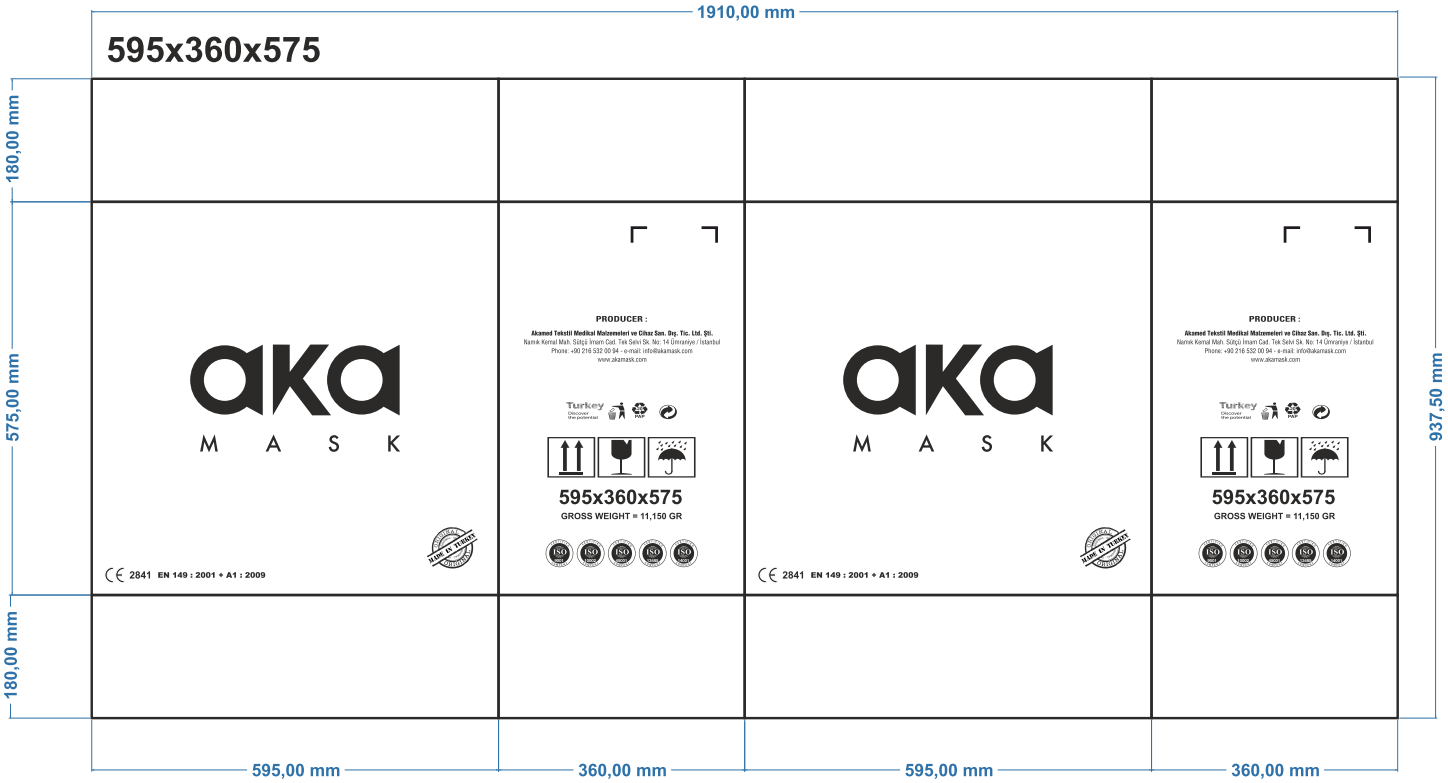


CE 2841 EN 149 : 2001 + A1 : 2009

C2 FFP2 NR

CE 2841 EN 149 : 2001 + A1 : 2009

C2 FFP2 NR



CE 2841 EN 149 : 2001 + A1 : 2009

Namık Kemal Mah. Sütçü İmam Cad.
Tek Selvi Sk. No: 14 Ümraniye / İstanbu
0216 532 00 94
info@akamask.com
www.akamask.com

EU-KONFORMITÄTSERKLÄRUNG

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

PRODUKTBESCHREIBUNG

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.
Tek Selvi Sk. No: 14 Ümraniye / İSTANBUL
Tel: 0216 532 00 94 www.akamask.com
ÜMRANİYE V.D.: 0120639696

CE
2841

Notified Body Number: 2841

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

Report No : 105-20-01-01

Report Date : 04.01.2021

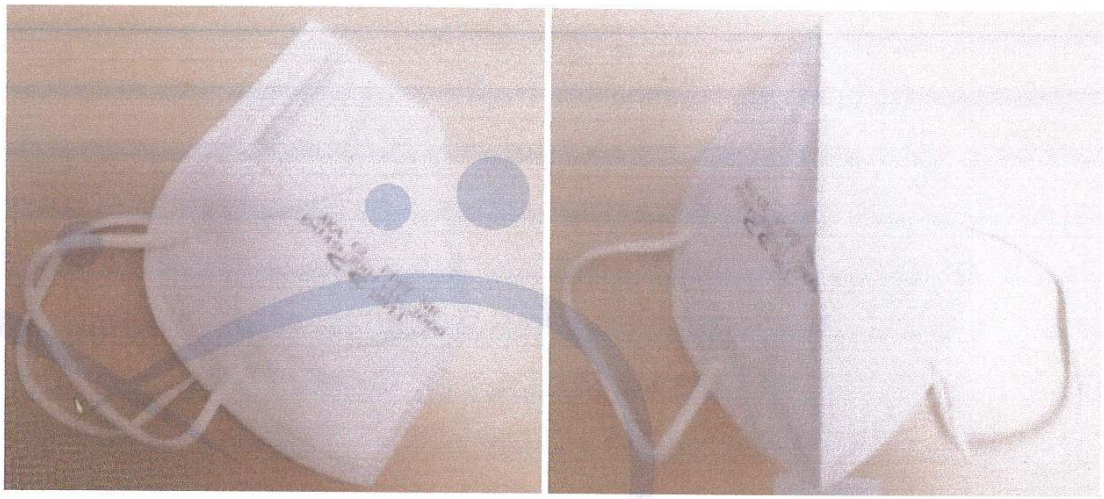
Application No : 105-20-01-01

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
   Tel: 0 216 532 00 94
   E-mail ilyas@akamask.com

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

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 fitler 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
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

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

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	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			
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

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. 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
- User Instruction

CONTROLLER : **ERHAN ÜSTÜNEL**

SING :

DATE : **04.01.2021**

MNA LABORATUVARLARI
Notified Body Number: 2841

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

Notified Body Number: 2841

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

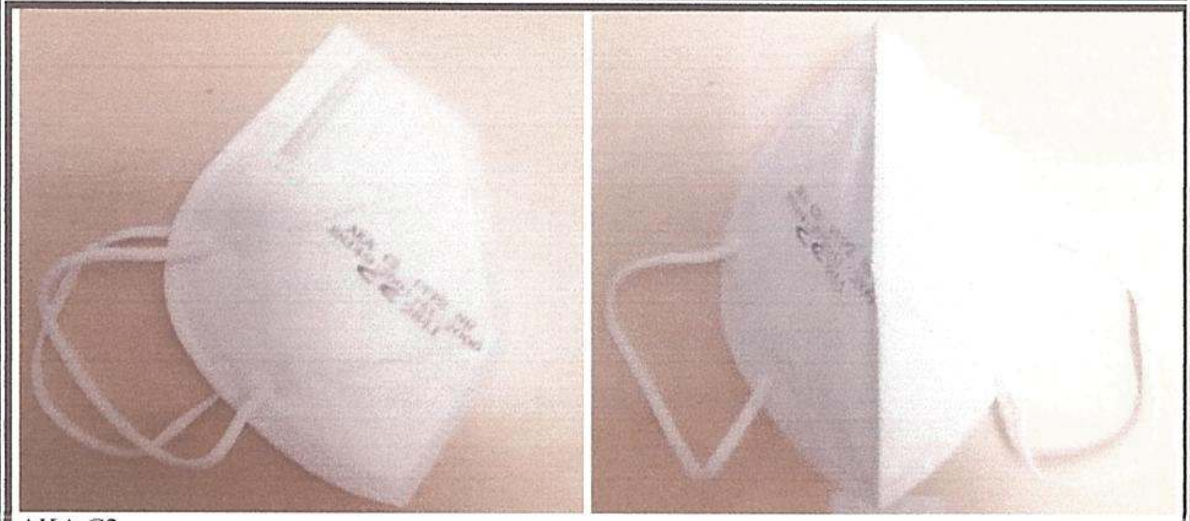
MODELL: AKA C2
PICTOGRAMM- UND LEISTUNGSSTUFEN:

EN 149:2001+ A1:2009 FFP2 NR

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

MNA LABORATUVARLARI
Notified Body Number: 2841

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. DIŞ. 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 katmanı kullanılarak imal edilmiştir./ *AKA C2 model products are manufactured using fabric, ear loop, nose clip, filter layer.*

Volkan AKIN	*Okan AKEL*
20.12.2020	*20.12.2020*
Karar Verici / Approver	*Şirket Müdürü / General manager*

Notified Body Number: 2841

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

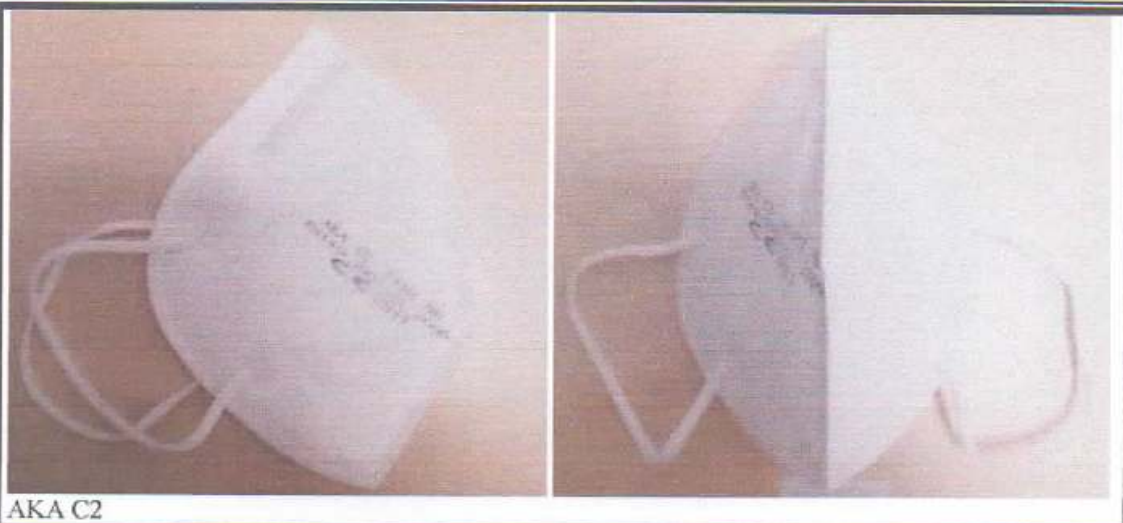
MODEL: AKA C2
PICTOGRAM AND PERFORMANCE LEVELS:

EN 149:2001+ A1:2009 FFP2 NR

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)

PRODUCT PICTURES

AKA C2

DOCUMENTS IN THE TECHNICAL
- Basic Health Safety Requirements - Risk Assessment - Test Reports - Technical Report

Report No :105-20-01

Report Date :20.12.2020

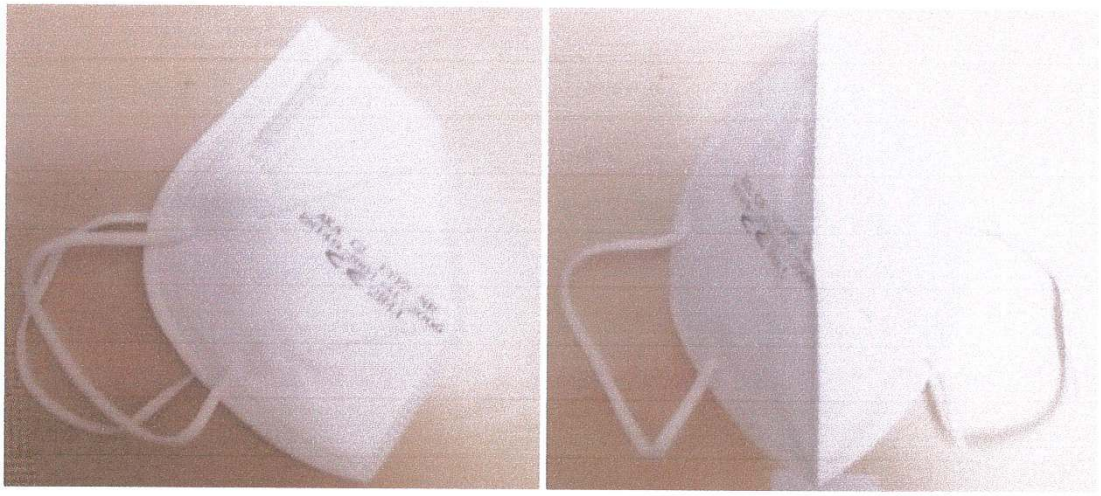
Application No :105-20-01

1. **COMPANY INFORMATION:**
   AKAMED TEKSTİL MEDİKAL MALZ. VE CİHAZ. SAN. DIŞ. TİC. LTD. ŞTİ.
   Namık Kemal Mah. Sütçü İmam Cad. Tek Selvi Sk. No: 14 Ümraniye / İstanbul
   Tel: 0 216 532 00 94
   E-mail ilyas@akamask.com

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

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, fitler 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
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

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

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**

PCA

PARTNERS CERTIFICATE ASSURANCE

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/ Istanbul/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

IAS ACCREDITED
Management Systems Certification Body
MSCB-103

PCA Sertifikasyon Onayı

PCA Sertifikasyon Hizmetleri Limited Şirketi
Orta Mah. Ordu Sk. İzpark C Blok No:26/23 Kartal / İSTANBUL
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www.pca-tr.com info@pca-tr.com

PCA
PARTNERS CERTIFICATE ASSURANCE

Sertifika

ISO 10002 : 2018

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

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

Bu sertifika yukarıdaki kuruluşa ait müşteri memnuniyeti 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

Sertifika No	: MM-70521
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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◆ ZERTIFIKAT ◆ CERTIFICATE ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

CERTIFICATE
OF REGISTRATION

This is to Certify that the

Medical Devices - Quality Management System

of

AKAMED TEKSTİL MEDİKAL MALZEME VE CİHAZLAR SANAYİ DIŞ TİCARET LİMİTED ŞİRKETİ

NAMIK KEMAL MAH. TEK SELVİ SOK. MOSS APT. NO:14
ÜMRANİYE / 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 ADEMOSU
Director

For verification and updated information concerning the present certificate visit to http://staunchlyservices.com/search_certified_client.php

This Certificate is the property of Staunchly Management & System Services Limited and shall be returned immediately when demanded

STAUNCHLY MANAGEMENT AND SYSTEM SERVICES LIMITED
Labrynth Business Centre, 43 Middle Hill Gate, Stockport,
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

IAS ACCREDITED Management Systems Certification Body MSCB125

SMS/FM/001/REV06

PCA

PARTNERS CERTIFICATE ASSURANCE

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/ Istanbul/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)

IAS ACCREDITED
Management Systems Certification Body
MSCB-103

PCA Sertifikasyon Onayı

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PCA
PARTNERS CERTIFICATE ASSURANCE

Sertifika

ISO 45001 : 2018

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

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

Bu sertifika yukarıdaki kuruluşa ait iş sağlığı ve güvenliği yönetim sisteminin aşağıdaki kapsam çerçevesinde PCA Sertifikasyon tarafından onaylandığını gösterm 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

PCA Sertifikasyon Hizmetleri Limited Şirketi
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