

Mascarilla FFP2 NR

UNIVERSAL

Verify the validity with the QR code.



EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-704

Respiratory protective devices, filtering half masks to protect against particles manufactured by
CHANGZHOU RUIDA MEDICAL TECHNOLOGY CO. LTD.
 No: 88 Mahang Middle Road, Hutang Town, Wujin District, Changzhou City, Jiangsu
 Province, China

are tested and evaluated according to

EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation.

Product Definition

Brand Name: ChangAnDa **Model:** CAD-01

Filtering half mask

Classification: FFP2 NR

Model have white, light blue, black, grey, purple, green, orange, rose, deep blue and yellow versions

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.**
- Ongoing successful performance in fulfilment of the requirements set out in Personal Protective Equipment Regulation (EU) 2016/425 and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation no later than 1 year from the beginning of serial production

This certificate is initially issued on **03/06/2020** and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.



Suat KACMAZ
 UNIVERSAL CERTIFICATION
 Director

This certificate is re-issued on 02.10.2020 with updated model name and colored versions of the model. The former model name was KN95. For details refer to the technical evaluation report provided to the manufacturer.

Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:44/84 Yakarlı Duhulu Ümraniye - İSTANBUL - TURKEY T: +90 216 455 80 80

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AB Tip İnceleme Sertifikası EU Type-Examination Certificate

Belge No / Certificate No : 147-21-03-R01
**Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /
Certification Date / Certificate Validity Date** : 23.08.2021-25.03.2026
Belge Geçerlilik Tarihi / Document Validity Period: 5 yıl / 5 years
**Firma Unvanı ve Adresi /
Company Name and Address** : DESANTE ELEKTRONİK TEKNOLOJİ DİŞ
TİC. A.Ş.
Beşyol Mah. Karadeniz Sk. Polaris Tekstil Blok
No: 4 İçk: 4 Küçükçekmece / İSTANBUL

Ürün Adı /Modeller / Product Name / Models : rosimask RM-12
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-2021-00402

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: rosimask RM-12 model ürünleri kumaş, elastik
kayış, burun klipsi ve filtre katmanı kullanılarak imal edilmiştir./ rosimask RM-12 model products are
manufactured using fabric, elastic strap, nose clip, filter layer.

Revizyon nedeni / Reason for revision: Firma bilgileri revize edilmiştir./ Company information has been
revised.

Volkan AKIN
23.08.2021

Karar Verici / Approver



Okan AKEL
23.08.2021

Şirket Müdürü / General manager




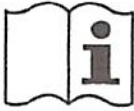
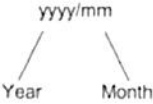

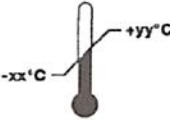

ATTACHMENTS (147-21-03-R01)

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 : rosimask RM-12

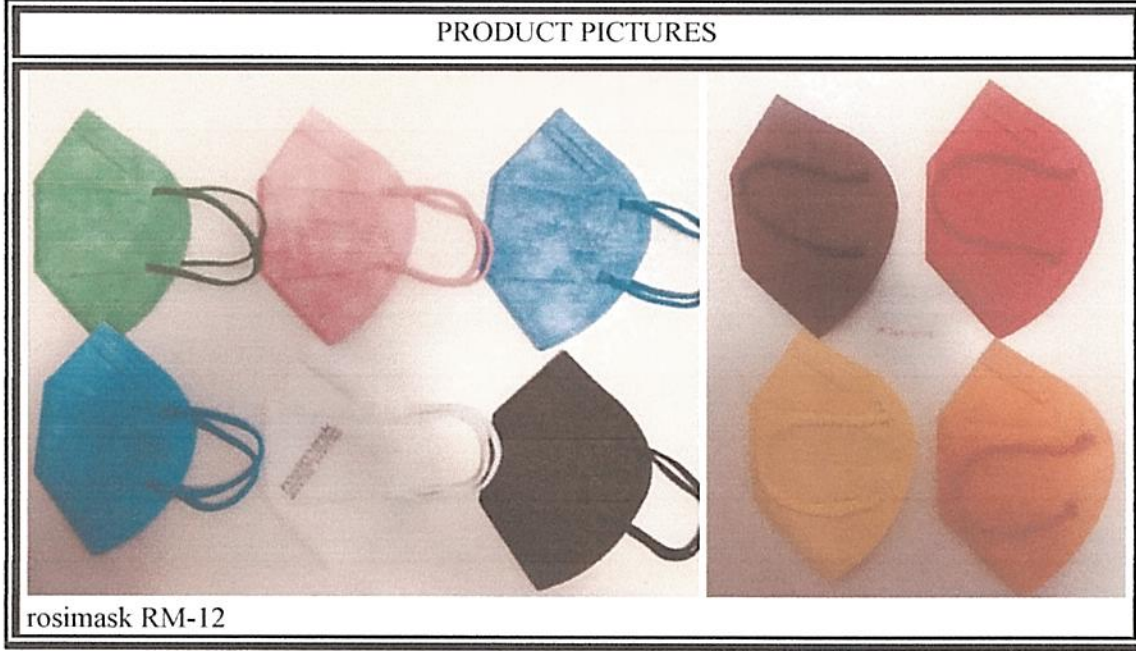
PPE SPECIFICATION	PERFORMANCE LEVELS
Classification	FFP2
Reusable / Single Shift Use	NR

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: DESANTE ELEKTRONİK TEKNOLOJİ DIŞ TİC. A.Ş.					
PPE TYPE :					
- EN 149:2001+ A1:2009 Respiratory protective devices - Filtering half masks to protect against particles					
MODEL: rosimask RM-12					
PRODUCT SIZE: S, L					
PICTOGRAM AND PERFORMANCE LEVELS:					
EN 149:2001+ A1:2009 FFP2 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 (147-21-03-R01)



DOCUMENTS IN THE TECHNICAL FILE

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

Report No : 147-21-03-R01

Report Date : 23.08.2021

Application No : 147-21-03-R01

1. COMPANY INFORMATION:

DESANTE ELEKTRONİK TEKNOLOJİ DİŞ TİC. A.Ş.

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

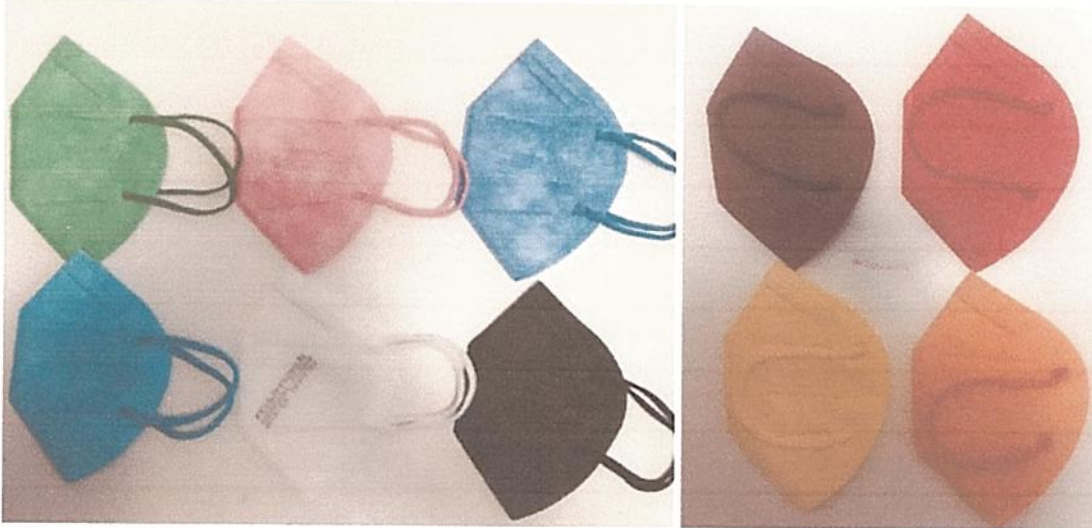
2. PPE INFORMATION:

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

3. PPE TYPE IDENTIFICATION

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

4. PPE PICTURES



rosimask RM-12

5. PPE DIMENSIONS:

rosimask RM-12 model has been found to be produced using small and large 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			
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

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)	7.0	6.9	7.9	8.1	8.2	7.6
Subject 2 (As recieved)	7.2	7.8	5.2	8.3	8.1	7.3
Subject 3 (As recieved)	7.3	8.8	7.9	7.5	7.9	7.9
Subject 4 (As recieved)	7.0	6.1	8.8	8.1	8.1	7.6
Subject 5 (As recieved)	6.7	6.5	9.0	9.4	8.1	7.9
Subject 6 (After temperature conditioning)	6.6	7.3	7.1	6.6	8.1	7.1
Subject 7 (After temperature conditioning)	6.4	7.6	7.0	7.9	10.5	7.9
Subject 8 (After temperature conditioning)	9.1	8.0	6.5	8.1	8.0	7.9
Subject 9 (After temperature conditioning)	6.7	6.9	6.6	7.9	6.5	6.9
Subject 10 (After temperature conditioning)	6.8	7.9	8.1	7.9	6.7	7.5

Subject facial dimensions

Subject	Face Length (mm)	Face Width (mm)	Face Depth (mm)	Mouth Width (mm)
1	133	132	132	65
2	125	144	116	67
3	126	135	124	75
4	123	133	134	74
5	117	135	122	73
6	122	142	133	66
7	113	132	114	75
8	135	123	123	65
9	122	135	133	74
10	135	142	125	83

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Part 7.9.2 Penetration of filter material	Sodium chloride, 95 L/min %, max	% 20	% 6	% 1	See the table below	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	4.1	4.2
As recieved	3.9	4.3
As recieved	4.1	4.2
After the simulated wearing treatment	4.2	4.6
After the simulated wearing treatment	4.3	4.9
After the simulated wearing treatment	4.3	4.8
Mechanical strength and temperature conditioning	5.5	5.6
Mechanical strength and temperature conditioning	5.3	5.4
Mechanical strength and temperature conditioning	5.4	5.6

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				0,81 0,84 0,79	-	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

Breathing Resistance (mbar)	Inhalation 30L/min	Inhalation 95L/min
As recieved	0.5	1,9
As recieved	0.5	1,8
As recieved	0.5	1,9
After temperature conditioning	0.5	1,9
After temperature conditioning	0.5	1,9
After temperature conditioning	0.5	1,8
After the simulated wearing treatment	0.4	1,9
After the simulated wearing treatment	0.5	1,8
After the simulated wearing treatment	0.5	1,8

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	2,2	2,2	2,2	2,1	2,2
As recieved	2,2	2,2	2,2	2,1	2,2
As recieved	2,2	2,2	2,2	2,2	2,2

After temperature conditioning	2,1	2,2	2,2	2,2	2,2
After temperature conditioning	2,1	2,2	2,2	2,2	2,2
After temperature conditioning	2,1	2,2	2,1	2,2	2,2
After the simulated wearing treatment	2,2	2,2	2,2	2,2	2,2
After the simulated wearing treatment	2,2	2,2	2,2	2,2	2,2
After the simulated wearing treatment	2,2	2,2	2,2	2,2	2,2

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 PROPOSAL

Analysis and examinations rosimask RM-12 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 : Company information has been revised.

CONTROLLER : VOLKAN AKIN

SIGNATURE :

DATE : 23.08.2021



EU-Konformittserklrung

EU-Declaration of Conformity

Dokument-Nr. / Document No. 202008

Wir / we : Desante Elektronik Teknoloji DıŐ Ticaret A.Ő
BeŐyol Mah. Karadeniz Sk. No:4 Kat:4 Kkekmece/İstanbul/ Trkiye

erklren in alleiniger Verantwortung, dass das Produkt
declare under our sole responsibility that the product

Partikelfiltrierende Halbmaske
Name/Typ: RM-2 , Marke/Brand:ROSIMASK
(Groen: Standardgroe) (Sizes: Standard size)
Particle filtering half mask
Classification FFP2 NR

mit der EU-Baumusterprufbescheinigung

is in conformity with the EU-Type Examination Certificate M-2021-00037,M-2021-00521

ausgestellt von der notifizierten Stelle mit
der Kenn-Nr.
issued by the Notified Body with Identification
No: 2841

Name und Anschrift der notifizierten Stelle
MNA Laboratuvarları san. Tic. Ltd. Őti.
Kkbakkalky Mahallesi YenidoŐan Caddesi No.21
AtaŐehir/İst/Trkiye

und mit der folgenden Harmonisierungsrechtsvorschrift der Union unter Anwendung der
aufgefhrten Norm bereinstimmt:

and is in compliance with the following Union harmonisation legislation by application of the listed
standard

Bestimmungen der Verordnung provisions of regulation		Nummer sowie Ausgabedatum der Norm Number and date of issue of standard
Verordnung (EU) 2016/425	Verordnung ber persnliche Schutzausrstungen Personal Protective Equipment Regulation	EN 149:2001+A1:2009

- o oder: berwachung der Konformitt mit der Bauart auf der
Grundlage einer internen Fertigungskontrolle mit berwachten
Produktprufungen in unregelmigen Abstnden (Modul C2) durch:
*Surveillance of conformity to type based on internal production control
plus supervised product checks at random intervals (Module C2)*
by: MNA Laboratuvarları san. Tic. Ltd. Őti.
Kkbakkalky Mahallesi YenidoŐan Caddesi No.21 AtaŐehir/İst/Trkiye
Zertifikat-Nr. 147-21-01-R01
Certificate No.

İstanbul/24.08.2021

Ort und Datum
Place and date

Cevdet Darende
General Manager

Name/Funktion
Name/Function

DESANTE ELEKTRONİK
TEKNOLOJİ DİŐ TİCARET A.Ő.
BeŐyol Mah. Karadeniz Sk. No:4 Kat:4
Kkekmece/İSTANBUL
Kkbakkalky Mahallesi YenidoŐan Caddesi No:21
AtaŐehir/İst/Trkiye
Tic. Sic. No: 249665-5