SECUOYA MANAGEMENT
TRADING IMPORT-EXPORT

CERTIFICACIÓN DE MASCARILLA FFP2 DE COLORES

Descripción del Producto

Mascarilla FFP2 sin válvula NO-MEDICA de diversos colores según el estándar EN 149:2001 + A1:2009 NO reutilizables. Estas mascarillas se han certificado en Universal, centro autorizado localizado en Turquía con un número de informe **CE-2163-PPE-704,** posteriormente se han evaluado los tintes de colores en SGS.

- Ancho 20 cm * largo 22 cm con banda metálica para ajuste nasal
- Filtración mayor al 99% de acuerdo con los tests realizados BFE > 98%
- Elástico de ajuste suaves para un ajuste confortable en ambos pabellones auditivos
- Fabricante: Changzhou Ruida, Hecha en China
- Marca: Chang An Da
- 11 colores disponibles.

Organismo Notificado.

Universal Certification and Surveillance Service Trade Ltd. Co.

Dirección: Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No: 44/84 Yukarı Dudullu, Ümraniye-Istanbul, Turquía

Teléfono: +90 216 455 80 80

Email: info@universalcert.com

Website: www.universalcert.com

Número de organismo notificado: **2163**

Composición:

MATERIAL	Peso	Estructura
100% Polipropileno	100gr/m2	Capa exterior
Tejido “Melt Blown”	30gr/m2	3 capas filtrantes
100% Polipropileno	40 gr/m2	Capa interior

Packaging:

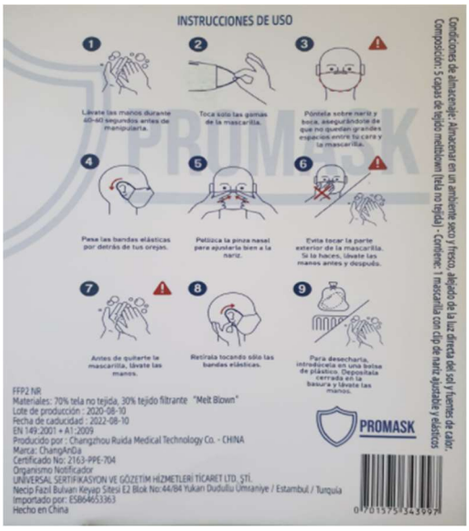
- 1 mascarilla por bolsa individual, en cajas de 25
- 1000 mascarillas por cartón
- Medidas del cartón: 65x40x30 cm con un peso bruto por cartón de 8 kgs.

Normas

- Condiciones de almacenaje: Almacenar en un ambiente seco y fresco, alejado de la luz directa del sol y fuentes de calor.
- Certificación: CE EN 149:2001 + A1.2009 Mascarillas FFP2 NO reutilizables.
- Este dispositivo es equipo de protección individual en el sentido del Reglamento UE / 2016/425
- Colores disponibles: Negro, amarillo, naranja, violeta, verde oscuro, verde claro, azul claro, turquesa, azul oscuro, rosa, gris.

Detalles del Producto

Unidad:



Certificado CE

UNIVERSAL

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NB 2163

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:** KN95
Filtering half mask
Classification: FFP2 NR

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.

CE 2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code

Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:44/84 Yukarı Dudullu Ümraniye - İSTANBUL - TURKEY T:+90 216 455 80 80
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Test Report FFP2

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UNIVERSAL CERTIFICATION and SURVEILLANCE SERVICES TRADE CO.
Necip Fazil Bulvari Keyap Sitesi E2 Blok No:44/84 Yukari Dudullu Umraniye, Istanbul / TURKEY

TEST REPORT

Report Date: 26.05.2020
Report Number: 05-2020-T-095

CLIENT and SAMPLE INFORMATION

TEST OWNER	Changzou Ruıda Medical Technology Co. Ltd.		
ADDRESS	No: 88 Mahang Middle Road, Hutang Town, Wujin District, Changzhou City, Jiangsu Province China		
SAMPLE DESCRIPTION	Vertical flat fold (See end of test report for sample photo)		
BRAND NAME – MODEL	PROMASK / KN 95		
TESTING STANDARD	EN 149+A1:2009		
CASE NUMBER	CE-PPE-2078		
SAMPLE RECEIVE DATE	11.05.2020	TESTING START DATE	12.05.2020
DISINFECTION INSTRUCTION *If applicable*	Not given, single use only		
NUMBER OF SAMPLES	50	SAMPLE IDs:	1 – 46
AS RECEIVED SAMPLE NO	26-46		
CONDITIONING SAMPLE NO	Simulated wearing treatment	1-2-3-4-5-6-7-8-9 (As Received)	
	Temperature conditioning	10-11-12-13-14-15 (Sample after test of Mechanical Strength)	
		16-17-18-19-20-21-22-23-24-25 (As Received)	
	Mechanical strength	10-11-12-13-14-15 (As Received)	

The results given in this test report belongs to the samples tested. The report content cannot be recreated partially without the written consent of UNIVERSAL CERTIFICATION.

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Necip Fazıl Bulvarı, Keyap Sitesi, E2 Blok, No:44/84 Yukarı Dudullu-Ümraniye, İSTANBUL
Telefon: 0216 455 80 80 Faks: 0216 455 80 08
Sarıgazi Ş.Ş. 1. Ş.

Suat KAÇMAZ
Director

UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZM. TİC. LTD. ŞTİ. Keyap Ticaret Merkezi, Necip Fazıl Bulvarı, E2 Blok, No:44/84 Y. Dudullu - Ümraniye - İSTANBUL T:+90 216 455 80 80 F:+90 216 455 80 08 info@universalcert.com

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1. *REPORT SUMMARY*

TEST STANDARD	*TEST NAME*	*RESULT*	*EVALUATION*
EN 149:2001 + A1:2009 clause 8.5 EN 13274-1:2001	Total Inward Leakage Testing	**Pass**	**FFP2**
EN 149:2001 + A1:2009 clause 8.11 EN 13274-7:2019	Penetration of Filter Material	**Pass**	**FFP2**
EN 149:2001 + A1:2009 clause 8.6 EN 13274-4:2001	Flammability Testing	**Pass**	**See result**
EN 149:2001 + A1:2009 clause 8.7 EN 13274-6:2001	Carbon Dioxide Content of The Inhalation Air Testing	**Pass**	**See result**
EN 149:2001 + A1:2009 clause 8.9 EN 13274-3:2001	Breathing Inhalation Resistance-30 l/min	**Pass**	**See results**
	Breathing Inhalation Resistance-95 l/min	**Pass**	**See results**
EN 149:2001 + A1:2009 clause 8.9 EN 13274-3:2001	Exhalation Resistance, flow rate 160 l/min	**Pass**	**See result**

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2. *TEST RESULTS and EVALUATION*

7.4 PACKAGING (EN 149:2001 + A1:2009 clause 8.2)

Test Method: Clause 8.2-Visual inspection

REQUIREMENT	RESULTS	COMMENT
Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.	Pass	The masks were packaged in sealed plastic bags, in larger plastic bags inside a large cardboard box that gave some protection against mechanical damage or contamination before use

Lab A

7.5 MATERIAL (EN 149:2001 + A1:2009 clause 8.2, 8.3.1, 8.3.2)

Test Method: Clause 8.2-Visual inspection

Clause 8.3.1-Simulated wearing treatment

A breathing machine is adjusted to 25 cycles/min and 2,0 l/stroke. The particle filtering half mask was mounted on a Sheffield dummy head.

For testing, a saturator is incorporated in the exhalation line between the breathing machine and the dummy head, the saturator being set at a temperature in excess of 37 °C to allow for the cooling of the air before it reaches the mouth of the dummy head.

The air has been saturated at (37 ± 2) °C at the mouth of the dummy head

Clause 8.3.2-Temperature conditioning

The ambient temperature for testing has been between 16 °C and 32 °C and the temperature limits has been subject to an accuracy of ±1 °C.

a) for 24 h to a dry atmosphere of (70 ± 3) °C;

b) for 24 h to a temperature of (-30 ± 3) °C; and allow to return to room temperature for at least 4 h between exposures and prior to subsequent testing. The conditioning has been carried out in a manner which ensures that no thermal shock occurs.

REQUIREMENT	RESULTS	COMMENT
Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used.	Pass	The materials used were able to withstand handling and wear during the limited laboratory testing carried out.
Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	Pass	It was not constitute a hazard or nuisance for the wearer.
After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.	Pass	None of the specimens conditioned suffered mechanical failure.
When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.	Pass	None of the specimens had not collapse after conditioning.

Lab B

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7.6 CLEANING AND DISINFECTING (EN 149:2001 + A1:2009 clause 8.4, 8.5, 8.11)

Test Method: Described in Clause 8.4, 8.5 and 8.11

REQUIREMENT	RESULTS	COMMENT
If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer. With reference to 7.9.2, after cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class.	N/A	This article is not applicable for tested protective mask which is single use disposable mask.

7.7 PRACTICAL PERFORMANCE (EN 149:2001 + A1:2009 clause 8.4)

Test Method: Described in Clause 8.4

REQUIREMENT	RESULTS	COMMENT
The particle filtering half mask shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that can not be determined by the tests described elsewhere in this standard.	No imperfections	Detail refer to Annex I

Annex I-Test Result:

Number of sample: 29 (A.R), 30 (A.R)

Assessed elements	Positive Assessment	Negative Assessment	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity
The face piece fitting	2	0	Filtering half masks should not have imperfections related to wearer's acceptance	Filtering half masks fulfil requirements of the standard EN 149:2001 + A1:2009 given in 7.7
Head harness comfort	2	0		
Security of fastenings	2	0		
Speech clearness	2	0		
Field of vision	2	0		
Materials compatibility with skin	2	0		No imperfections

Lab B

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7.8 FINISH OF PARTS (EN 149:2001 + A1:2009 clause 8.2)

Test Method: Described in Clause 8.2

REQUIREMENT	RESULTS	COMMENT
Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	Pass	None of the specimens used in laboratory testing showed evidence of sharp edges or burrs.

Lab A

7.9.1 TOTAL INWARD LEAKAGE (EN 149:2001 + A1:2009 clause 8.5)

Test Method: Described in Clause 8.5

REQUIREMENT	RESULTS	COMMENT
The total inward leakage consists of three components: face seal leakage, exhalation value leakage (if exhalation value fitted) and filter penetration. For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual results shall be not greater than: 25 % for FFP1, 11 % for FFP2, 5 % for FFP3 and in addition at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall not be greater than: 22 % for FFP1, 8 % for FFP2 2 % for FFP3	Pass	Classified as FFP2 Detail refer to Annex II

Annex II-Test Result:
The test results obtained are given in the tables as follows

Test Subject	No of sample	Cond.	1. Walk (%)	Head side/ side (%)	Head up/down (%)	Talk (%)	2. Walk (%)	Mean (%)
1	31	A.R.	6,4	5 47	4,15	6,13	6,79	5,87
2	32	A.R.	6,53	4,45	6,17	7,29	7,45	6,38
3	33	A.R.	7,36	6,92	7,1	6,19	7,12	6,94
4	34	A.R.	6,33	5,24	7,32	6,26	7,4	6,51
5	35	A.R.	6,81	6,41	7,5	6,12	8,22	7,01
6	16	T.C.	5,63	7,45	6,75	7,21	6,2	6,65
7	17	T.C.	6,85	7,8	7,61	6,29	7,32	7,17
8	18	T.C.	7,69	7,9	8,96	8,28	8,19	**8,2**
9	19	T.C.	7,58	8,19	7,37	7,6	9,2	7,99
10	20	T.C.	7,57	7,41	7,42	7,76	8,87	7,81
All 50 individual exercise results were not greater than 11 % At least 9 of 10 individual wearer arithmetic means were not greater than 8 %								Pass (FFP2)

Lab B

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7.9.2 PENETRATION OF FILTER MATERIAL (EN 149:2001 + A1:2009 clause 8.11)

Test Method: Described in Clause 8.11

REQUIREMENT			RESULTS	COMMENT
Classification	Max penetration of test aerosol			
	NaCl test 95 l/min %max	Paraffin oil test 95 l/min %max		
FFP1	20	20	Pass	Detail refer to Annex IIIA and IIIB
FFP2	6	6		
FFP3	1	1		

Annex IIIA-Test Result:

The test results obtained are given in the tables as follows:

No. of Sample	Condition	Penetration of Sodium Chloride in accordance with EN 13274-7:2019 [%] Flow rate 95 l/min	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity
36	As received	2,65	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	Passed Filtering half masks fulfil the requirements of the standard EN 149:2001+A1:2009 given in 7.9.2 in range of the first and second protection classes (FFP1, FFP2)
37		4,03		
38		5,07		
1	Simulated wearing treatment	2,70		
2		4,06		
3		5,10		
10	Mechanical strength + Temperature conditioned	2,68		
11		4,06		
12		5,09		

Annex IIIB-Test Result:

The test results obtained are given in the tables as follows:

No. of Sample	Condition	Penetration of Paraffin Oil Mist in accordance with EN 13274-7:2019 [%] Flow rate 95 l/min	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity
39	As received	3,97	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	Passed Filtering half masks fulfil the requirements of the standard EN 149:2001+A1:2009 given in 7.9.2 in range of the first and second protection classes (FFP1, FFP2)
40		3,18		
41		4,58		
4	Simulated wearing treatment	4,01		
5		3,20		
6		4,61		
13	Mechanical strength + Temperature conditioned	3,99		
14		3,21		
15		4,63		

Lab A + B

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7.10 COMPATIBILITY WITH SKIN (EN 149:2001 + A1:2009 clause 8.4, 8.5)

Test Method: Described in Clause 8.4 and 8.5.

REQUIREMENT	RESULTS	COMMENT
Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.	Pass	No irritation or any other adverse effect to health or sensitivity reported by the subjects.

Lab B

7.11 FLAMMABILITY (EN 149:2001 + A1:2009 clause 8.6)

Test Method: Described in Clause 8.6

REQUIREMENT	RESULTS	COMMENT
The material used shall not present a danger for the wearer and shall not be of highly flammable nature. When tested, the particle filtering half mask shall not burn or not to continue to burn 5s after removal from the flame.	Pass	Detail refer to Annex IV

Annex IV-Test Result:

The test results obtained are given in the tables as follows:

No. of Sample	Condition	Visual inspection	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity
45	As received	2,40	Filtering half mask shall not burn or not continue to burn for more than 5 s after removal from the flame	Passed Filtering half masks fulfil requirements of the standard EN 149:2001 + A1:2009 given in 7.11
46		2,08		
21	Temperature conditioned	2,19		
22		2,14		

Lab B

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7.12 CARBON DIOXIDE CONTENT OF THE INHALATION AIR (EN 149:2001 + A1:2009 clause 8.7)

Test Method: Described in Clause 8.7

REQUIREMENT	RESULTS	COMMENT
The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume)	Pass	Detail refer to Annex V

Annex V-Test Result:

The test results obtained are given in the tables as follows:

No. of Sample	Condition	CO_2 content of the inhalation air [%] by volume	An average CO_2 content of the inhalation air [%] by volume	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity
26	As received	0,49	0,57	CO_2 content of the inhalation air shall not exceed an average of 1,0% by volume	Passed Filtering half masks fulfil requirements of the standard EN 149:2001 + A1:2009 given in 7.12
27		0,64			
28		0,59			

Lab B

7.13 HEAD HARNESS (EN 149:2001 + A1:2009 clause 8.4, 8.5)

Test Method: Described in Clause 8.4, 8.5

REQUIREMENT	RESULTS	COMMENT
The head harness shall be designed so that the particle filtering half-mask can be donned and removed easily.	Pass	No problem with the head harness reported by the wearers during the practical performance test.
The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the particle filtering half mask firmly in position and capable of maintaining total inward leakage requirements for the device.	Pass	No problem with the head harness reported by the wearers during the practical performance test.

Lab B

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7.14 FIELD OF VISION (EN 149:2001 + A1:2009 clause 8.4)

Test Method: Described in Clause 8.4

REQUIREMENT	RESULTS	COMMENT
The field of vision is acceptable if determined so in practical performance tests.	Pass	There were no adverse comments following practical performance tests.

Lab B

7.15 EXHALATION VALVE (EN 149:2001 + A1:2009 clause 8.2, 8.3.4, 8.8, 8.9.1)

Test Method: Clause 8.2, 8.3.4, 8.8, 8.9.1

REQUIREMENT	RESULTS	COMMENT
A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.	N/A	No exhalation valve in tested samples.
If an exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device that may be necessary for the particle filtering half mask to comply with 7.9	N/A	No exhalation valve in tested samples.
Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30s.	N/A	No exhalation valve in tested samples.
When the exhalation valve housing is attached to the face blank, it shall withstand axially a tensile force of 10N applied for 10s.	N/A	No exhalation valve in tested samples.

Lab -

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7.16 BREATHING RESISTANCE (EN 149:2001 + A1:2009 clause 8.9)

Test Method: Described in Clause 8.9

REQUIREMENT	RESULTS	COMMENT
See table below	Pass	Classified as FFP3 Detail refer to Annex VIA-VIB

Classification	Max permitted resistance (mbar)		
	Inhalation		Exhalation
	30 l/min	95 l/min	160 l/min
FFP1	0.6	2.1	3.0
FFP2	0.7	2.4	3.0
FFP3	1.0	3.0	3.0

Annex VIA-Test Result:
The test results obtained are given in the tables as follows:

Inhalation Resistance

No. of Sample	Condition	Inhalation Resistance (mbar)				
		Flow rate 30 l/min	Requirements in accordance with EN 149:2001+A1:2009	Flow rate 95 l/min	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity
42	As received	0,36	FFP1 ≤ 0,60 FFP2 ≤ 0,70 FFP3 ≤ 1,0	1,21	FFP1 ≤ 2,10 FFP2 ≤ 2,40 FFP3 ≤ 3,00	Passed
43		0,38		1,25		Passed
44		0,37		1,23		Passed
7	Simulated wearing treatment	0,38		1,23		Passed
8		0,40		1,27		Passed
9		0,39		1,26		Passed
23	Temperature conditioned	0,37		1,25		Passed
24		0,38		1,28		Passed
25		0,38		1,29		Passed

Exhalation Resistance

No. of Sample	Condition	Flow rate	Facing directly	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity
42	As received	160l/min	2,18	2,20	2,21	2,20	2,21	FFP1 ≤ 3,0 FFP2 ≤ 3,0 FFP3 ≤ 3,0	Passed
43			2,23	2,25	2,25	2,27	2,29		Passed
44			2,24	2,26	2,27	2,30	2,31		Passed
7	Simulated wearing treatment		2,20	2,22	2,25	2,28	2,26		Passed
8			2,25	2,30	2,32	2,33	2,30		Passed
9			2,27	2,29	2,30	2,30	2,31		Passed
23	Temperature conditioned		2,21	2,22	2,25	2,27	2,26		Passed
24			2,26	2,28	2,30	2,31	2,30		Passed
25			2,29	2,31	2,32	2,34	2,32		Passed

Lab A

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7.17 CLOGGING (EN 149:2001 + A1:2009 clause 8.9, 8.10)

Test Method: Described in Clause 8.8, 8.10

REQUIREMENT	RESULTS	COMMENT
Valved particle filtering half masks: After clogging the inhalation resistances shall not exceed: FFP1:4mbar, FFP2:5mbar, FFP3:7mbar at 95L/min continuous flow. The exhalation resistance shall not exceed 3mbar at 160L/min continuous flow. Valveless particle filtering half masks: After clogging the inhalation resistances shall not exceed: FFP1:3mbar, FFP2:4mbar, FFP3:5mbar at 95L/min continuous flow	NAs	This is optional test and not desired by client.

Lab -

7.18 DEMOUNTABLE PARTS (EN 149:2001 + A1:2009 clause 8.2)

Test Method: Described in Clause 8.2

REQUIREMENT	RESULTS	COMMENT
All demountable parts (if fitted) shall be readily connected and secured, where possible by hand	N/A	No demountable part.

Lab -

Pass	*Requirement satisfied.*
NCR	*Requirement not satisfied. Refer to the "Result details" section for more information.*
NAs	*Assessment not carried out.*
N/A	*Requirement not applicable.*

LABORATORY INFORMATION

Code	Laboratory Name	Competency Explanations
Lab A	UNIVERSAL SERTIFIKASYON VE GOZETIM HIZMETLERI TIC. LTD. STI.	Internal Laboratory Services of Notified Body
Lab B	GCNTR ULUSLARARASI BELGELENDIRME, GOZETIM, EGITIM VE DIS TICARET LIMITED SIRKETI KOCAELI DILOVA SUBESI	Laboratory holds an accreditation by Turkish Accreditation Agency with number AB-1252-T according to EN ISO/IEC 17025:2017.

- The laboratories are contracted bodies with UNIVERSAL CERTIFICATION and the technical competence of the laboratories is also under supervision / assessment of UNIVERSAL CERTIFICATION based on the provisions of EN ISO/IEC 17065 Requirements for bodies certifying products, processes and services standard.
- Each test result given in this test report shown with the issuing laboratory code.

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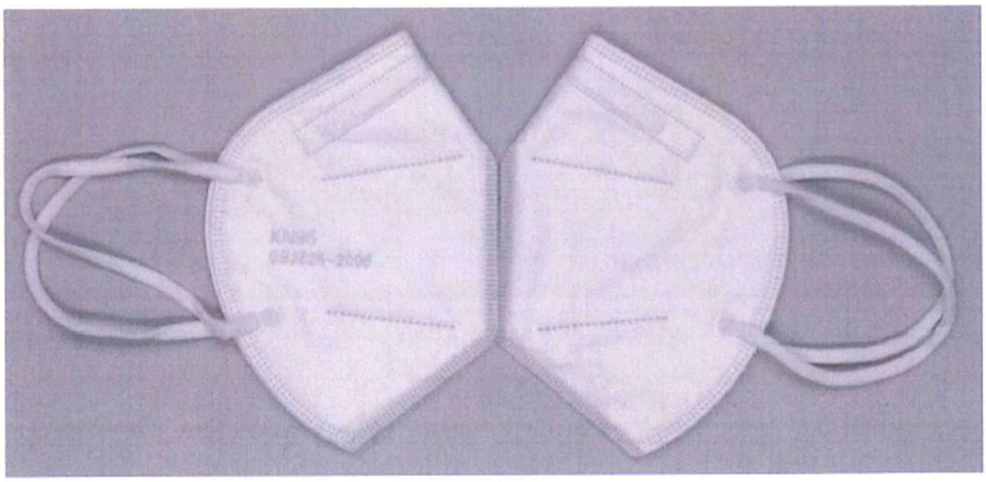
UNIVERSAL
CERTIFICATION

Sample Photo



- End of Report -

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Test tintes de colores

SGS

SDS Report No.: CANML2014109701 Date: 19 Aug 2020 Page 1 of 1

CHANGZHOU RUIDA MEDICAL TECHNOLOGY CO.,LTD
NO.88 MAHANG MIDDLE ROAD,HUTANG TOWN,WUJIN DISTRICT,CHANGZHOU CITY,JIANGSU PROVINCE,CHINA

SGS Job No.	:	GZIN2008043399PC
Sample Name	:	non-woven fabric
End Uses	:	Make masks
Composition/Ingredient of sample (as per client submission)	:	See *section 3 Composition/information on ingredients* on the SDS report
Job Receiving Date	:	14 Aug 2020
SDS Preparation Period	:	14 Aug 2020-19 Aug 2020
Service Requested	:	Safety Data Sheet (SDS) for the sample with submitted composition.
Summary	:	As per request, the contents and formats of the SDS are prepared in accordance with European Commission Regulation (EC) No 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) No 2015/830, and is provided per attached.

Remark:
The SDS is prepared based on the information provided by client.

* This sample is likely to be classified as article with substances not intended to be released and is out of scope of a SDS as set out in Regulation (EC) No 1907/2006. This SDS is generated for client's reference only.

Signed for and on behalf of
SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch

Zmguan

Zm guan
Approved Signatory

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Attention: To check the authenticity of testing /inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com

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中国·广州·经济技术开发区科学城科珠路198号 邮编: 510663 t (86-20) 82155555 f (86-20) 82075113 e sgs.china@sgs.com

Member of the SGS Group (SGS SA)

Safety data sheet
Regulation (EC) No. 1907/2006 and 1272/2008

Printing date 19.08.2020 Version number 1 Revision: 17.08.2020

SECTION 1: Identification of the substance/mixture and of the company/undertaking

· **1.1 Product identifier**

· **Trade name:** non-woven fabric

· **1.2 Relevant identified uses of the substance or mixture and uses advised against**
· **Application of the substance / the mixture:** Make masks

· **1.3 Details of the supplier of the safety data sheet**
· **Manufacturer / Supplier:** CHANGZHOU RUIDA MEDICAL TECHNOLOGY CO.,LTD
· **Full address:**
NO.88 MAHANG MIDDLE ROAD,HUTANG TOWN,WUJIN DISTRICT,CHANGZHOU CITY,JIANGSU PROVINCE,CHINA
· **Phone number:** 13151282825
· **Email:** 768719541@qq.com

· **Only Representative / other EU contact point:** Not available

· **Further information obtainable from:** CHANGZHOU RUIDA MEDICAL TECHNOLOGY CO.,LTD

· **1.4 Emergency telephone number:**
GERMANY
Poison Center Berlin - Institute of Toxicology
Tel: +49 030 192 40

· **1.5 Reference Number:** CANML2014109701,GZIN2008043399PC

· **1.6 Remark:**
* This sample is likely to be classified as article with substances not intended to be released and is out of scope of a SDS as set out in Regulation (EC) No 1907/2006. This SDS is generated for client's reference only.

SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**
· **Classification according to Regulation (EC) No 1272/2008**
The product is not classified according to the CLP regulation.

· **Information concerning particular hazards for human and environment:**
The product has not to be labelled due to the calculation procedure of Regulation (EC) No. 1272/2008.

· **Classification system:**
The classification is according to the latest edition of EU Regulation (EC) No. 1272/2008, and extended by company and literature data.

· **2.2 Label elements**
· **Labelling according to Regulation (EC) No. 1272/2008** Void
· **Hazard pictograms** Void
· **Signal word** Void
· **Hazard statements** Void

· **2.3 Other hazards:**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· **3.2 Mixtures**
· **Description:**
Mixture of the substances listed below with nonhazardous additions.
For the wording of the listed hazard statements refer to section 16.

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Trade name: non-woven fabric

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· **Composition:**

CAS: 9003-07-0	Polypropylene	99.99%
CAS: 481-74-3 EINECS: 207-572-2	1,8-dihydroxy-3-methylanthraquinone	0.01%

· **Remark:** All ingredients listed above are not classified according to Regulation (EC) No. 1272/2008.

SECTION 4: First aid measures

· **4.1 Description of first aid measures**
· **General description:** No special measures required.
· **After inhalation:** Supply fresh air; consult doctor in case of complaints.
· **After skin contact:** Generally the product does not irritate the skin.
· **After eye contact:** Rinse opened eye for several minutes under running water.
· **After swallowing:** If symptoms persist consult doctor.

· **4.2 Most important symptoms and effects, both acute and delayed:**
No further relevant information available.

· **4.3 Indication of any immediate medical attention and special treatment needed:**
No further relevant information available.

SECTION 5: Firefighting measures

· **5.1 Extinguishing media**
· **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.

· **5.2 Special hazards arising from the substance or mixture:** No further relevant information available.

· **5.3 Advice for firefighters**
· **Protective equipment:** No special measures required.

SECTION 6: Accidental release measures

· **6.1 Personal precautions, protective equipment and emergency procedures:** Not required.

· **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.

· **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.

· **6.4 Reference to other sections:**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

· **7.1 Precautions for safe handling:**
No special measures required.
For the general occupational hygienic measures refer to Section 8.
· **Information about fire - and explosion protection:** No special measures required.

· **7.2 Conditions for safe storage, including any incompatibilities**
· **Requirements to be met by storerooms and receptacles:** No special requirements.
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:** None.

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Trade name: non-woven fabric

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· **7.3 Specific end use(s):** No further relevant information available.

SECTION 8: Exposure controls/personal protection

· **8.1 Control parameters**
· **Ingredients with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
· **DNELs:** Not available
· **PNECs:** Not available

· **Additional information:** The lists valid during the making were used as basis.

· **8.2 Exposure controls**
Based on the composition shown in Section 3, the following measures are suggested for occupational safety measure.
· **Appropriate engineering controls:** See Section 7 for information about design of technical facilities.

· **Personal protective equipment**
· **Respiratory protection:** Not required.
· **Protection of hands:**

Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.
· **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
· **Penetration time of glove material:**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Eye protection:** Not required.
· **Environmental exposure controls:**
Control measures must be made in accordance with Community environmental protection legislation.

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**
· **Appearance**

Form:	Solid
Colour:	Rhubarb
· **Odour:**	Odourless
· **Odour threshold:**	Not available
· **pH-value:**	Not available
· **Change in condition**	
Melting point/Freezing point:	Not available
Initial boiling point and boiling range:	Not available

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· **Flash point:**	Not available
· **Flammability (solid, gas):**	Not available
· **Auto-ignition temperature:**	Not available
· **Decomposition temperature:**	Not available
· **Self-igniting:**	Product is not selfigniting.
· **Explosive properties:**	Product does not present an explosion hazard.
· **Explosion limits**	
Lower:	Not available
Upper:	Not available
· **Oxidising properties:**	Not available
· **Vapour pressure:**	Not available
· **Density:**	Not available
· **Relative density:**	Not available
· **Vapour density:**	Not available
· **Evaporation rate:**	Not available
· **Solubility in / Miscibility with water:**	Not available
· **Partition coefficient: n-octanol/water:**	Not available
· **Viscosity**	
Dynamic:	Not available
Kinematic:	Not available
· **9.2 Other information**	No further relevant information available.

SECTION 10: Stability and reactivity

· **10.1 Reactivity:** Data not available

· **10.2 Chemical stability:** Data not available

· **10.3 Possibility of hazardous reactions:** No dangerous reactions known.

· **10.4 Conditions to avoid:** No further relevant information available.

· **10.5 Incompatible materials:** No further relevant information available.

· **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

SECTION 11: Toxicological information

· **11.1 Information on toxicological effects**
· **Acute toxicity** Based on available data, the classification criteria are not met.
· **LD/LC50 values relevant for classification:** Not available
· **Skin corrosion/irritation:** Based on available data, the classification criteria are not met.
· **Serious eye damage/irritation:** Based on available data, the classification criteria are not met.
· **Respiratory or skin sensitization:** Based on available data, the classification criteria are not met.
· **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
· **Carcinogenicity** Based on available data, the classification criteria are not met.
· **Reproductive toxicity** Based on available data, the classification criteria are not met.
· **STOT-single exposure** Based on available data, the classification criteria are not met.
· **STOT-repeated exposure** Based on available data, the classification criteria are not met.

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· **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

· **12.1 Toxicity**
· **Aquatic toxicity:** No further relevant information available.

· **12.2 Persistence and degradability:** No further relevant information available.

· **12.3 Bioaccumulative potential:** No further relevant information available.

· **12.4 Mobility in soil:** No further relevant information available.

· **12.5 Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

· **12.6 Other adverse effects** No further relevant information available.

· **12.7 Additional ecological information:**
· **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

SECTION 13: Disposal considerations

· **13.1 Waste treatment methods**
· **Recommendation:** Smaller quantities can be disposed of with household waste.

· **Uncleaned packaging**
· **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

· **14.1 UN-Number**	
· **ADR/RID/ADN, IMDG, IATA**	Not applicable
· **14.2 UN proper shipping name**	
· **ADR/RID/ADN, IMDG, IATA**	Not applicable
· **14.3 Transport hazard class(es)**	
· **ADR/RID/ADN, IMDG, IATA**	
· **Class**	Not applicable
· **Label**	-
· **14.4 Packing group**	
· **ADR/RID/ADN, IMDG, IATA**	Not applicable
· **14.5 Environmental hazards**	
· **Marine pollutant:**	No
· **14.6 Special precautions for user:**	Not applicable
· **Danger code (Kemler):**	-
· **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**	Not applicable
· **14.8 Transport/Additional information:**	Not dangerous according to the above specifications.

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Trade name: non-woven fabric

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· **UN "Model Regulation":** Void

SECTION 15: Regulatory information

· **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **MAK(German Maximum Workplace Concentration)**

None of the ingredients is listed.

· **Directive 2012/18/EU**
· **Named dangerous substances - ANNEX I** None of the ingredients is listed.
· **Seveso category** Not applicable
· **Qualifying quantity (tonnes) for the application of lower-tier requirements** Not applicable
· **Qualifying quantity (tonnes) for the application of upper-tier requirements** Not applicable
· **National regulations:**

· **Waterhazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.

· **Other regulations, limitations and prohibitive regulations**

· **SVHC Candidate List of REACH Regulation Annex XIV Authorisation (25/6/2020)**

None of the ingredients is listed

· **REACH Regulation Annex XVII Restriction (20/06/2019)**
See Section 16 for information about restriction of use.

None of the ingredients is listed

· **REACH Regulation Annex XIV Authorisation List (06/2/2020)**

None of the ingredients is listed

· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

· **********

The contents and format of this SDS are in accordance with Regulation (EC) No 1907/2006, 1272/2008 and Regulation (EU) No 2015/830.

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Remark:
* This sample is likely to be classified as article with substances not intended to be released and is out of scope of a SDS as set out in Regulation (EC) No 1907/2006. This SDS is generated for client's reference only.

· **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)

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DNEL: Derived No-Effect Level (REACH)
PNEC: Predicted No-Effect Concentration (REACH)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative

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End of document