Mascarilla FFP2 NR – Talla M

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PARTIAL TEST REPORT

Report Date:08.10.2020
Report Number: 10-2020-T0415

CLIENT and SAMPLE INFORMATION

TEST OWNER	CHANGZHOU RUIDA MEDICAL TECHNOLOGY CO. LTD.		
ADDRESS	No: 88 Mahang Middle Road, Hutang Town, Wujin District, Changzhou City, Jiangsu Province, China		
SAMPLE DESCRIPTION	Folding type protective mask (Coloured - Size M)		
BRAND NAME – MODEL	ChangAnDa – CAD-01		
TESTING STANDARD	EN 149+A1:2009		
CASE NUMBER	CE-PPE-2078		
SAMPLE RECEIVE DATE	02.10.2020	TESTING START DATE	02.10.2020
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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PROMASK

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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	**NAs**	**-**
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	**NAs**	**-**
EN 149:2001 + A1:2009 clause 8.7 EN 13274-6:2001	Carbon Dioxide Content of The Inhalation Air Testing	**NAs**	**-**
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 results**

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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.

7.8 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 while visual inspection and performance tests.

Lab A

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
(see table below)	Pass	Detail refer to Annex IIIA and IIIB

Classification	Max penetration of test aerosol	
	NaCl test 95 l/min %max	Paraffin oil test 95 l/min %max
FFP1	20	20
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	0.55	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, second and third protection class (FFP1, FFP2)
37		0.83		
38		0.58		
1	Simulated wearing treatment	1.70		
2		1.28		
3		0.58		
10	Mechanical strength + Temperature conditioned	1.03		
11		1.34		
12		1.52		

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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	1,24	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, second third protection class (FFP1, FFP2)
40		1,63		
41		1,49		
4	Simulated wearing treatment	1,68		
5		1,65		
6		1,47		
13	Mechanical strength + Temperature conditioned	1,71		
14		2,98		
15		1,76		

Lab A + 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.	NAs	The model do not have valve
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	NAs	The model do not have valve
Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30s.	NAs	The model do not have valve
When the exhalation valve housing is attached to the face blank, it shall withstand axially a tensile force of 10N applied for 10s.	NAs	The model do not have valve

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 classification 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 [mbar]	Requirements in accordance with EN 149:2001+A1:2009	Flow rate 95 l/min [mbar]	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity
42	As received	0,58	FFP1 ≤ 0,60 FFP2 ≤ 0,70 FFP3 ≤ 1,0	1,68	FFP1 ≤ 2,10 FFP2 ≤ 2,40 FFP3 ≤ 3,00	Passed Qualifies FFP1, FFP2,FFP3
43		0,51		1,43		
44		0,55		1,50		
7	Simulated wearing treatment	0,53		1,67		
8		0,55		1,69		
9		0,60		1,73		
23	Temperature conditioned	0,62		1,76		
24		0,59		1,68		
25		0,57		1,49		

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	2,25	2,03	2,06	2,11	2,14	FFP1 ≤ 3,0 FFP2 ≤ 3,0 FFP3 ≤ 3,0	Passed Qualifies FFP1,FFP2, FFP3
43			1,83	2,16	1,98	2,12	2,15		
44			1,92	2,21	1,93	2,08	2,13		
7	Simulated wearing treatment		2,05	2,11	1,98	1,95	2,07		
8			2,03	2,06	1,95	2,04	2,01		
9			2,07	2,09	2,00	2,05	2,03		
23	Temperature conditioned		2,10	2,13	2,11	2,08	2,10		
24			2,06	2,15	2,09	2,13	2,08		
25			2,12	2,10	2,14	2,16	2,11		

Lab A

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.*

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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.

Sample Photo

- End of Report -

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