

Mascarilla FFP2 NR – Talla M



TECHNICAL ASSESSMENT REPORT

REPORT DATE / NO: 12.10.2020 / 2163-KKD-704 / R2

Initial Report Date and Number: 03.06.2020 / 2163-KKD-704

This technical evaluation report is updated with the model name update decision and also use of the same fabric as defined in the initial technical with colored versions in the outer most layer of the mask and earloops. The manufacturer also designed a smaller size (M) and named the initial design as standard size. The purpose of the change is to produce respectively smaller sized masks to better fit for those who have smaller face / chin when compared to general sizes of adults. One more purpose can be considered as to provide better fitting masks for younger people. There is no other design or material change in the colored or M size versions of the model. The Total Inward Leakage test is not conducted because of unavailability of subjects for the test. The smaller size (M) is tested for particle filtration efficiency and breathing resistance. See relevant test reports.

Manufacturer: CHANGZHOU RUIDA MEDICAL TECHNOLOGY CO. LTD.

Address: No: 88 Mahang Middle Road, Hutang Town, Wujin District, Changzhou City, Jiangsu Province, China

This report is for the, given above manufacturer, prepared according to the test results conducted by UNIVERSAL CERTIFICATION, dated 26.05.2020 with Serial No 05-2020-T-095 and dated 08.10.2020 with Serial No 10-2020-T-0415 based on EN 149: 2001 + A1: 2009 standard and test reports on the material safety by means of toxic, carcinogen, irritating and sensitivity evaluation.

The technical file of the manufacturer, and risk evaluation against the essential health safety requirements and the test report evaluated for their relation with Essential Requirements of Personal Protective Equipment Regulation and found to be appropriate.

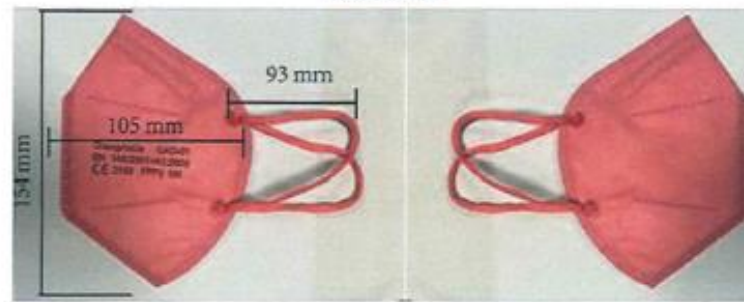
This report is an annex and an integral part of the EU Type Examination Certificate issued to the manufacturer. The test results and issued certificate belongs only to the tested model. The technical report consists of a total of 6 pages.

Product Description: Particle Filtering Half Mask

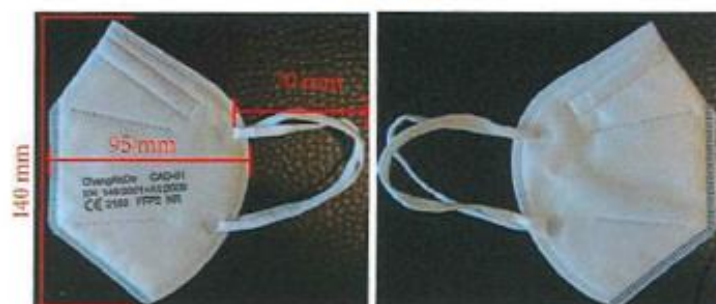
Classification: FFP2 NR

Brand Name: ChangAnDa **Model:** CAD-01 (*Former model name was KN95*), **Sizes:** Standard - Medium

Standard Size



Medium Size



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**THE CLAUSES OF EN 149: 2001 + A1: 2009 STANDARD RELATED TO EUROPEAN UNION DIRECTIVE
EU 2016/425 REQUIREMENTS**

1.1. Design principles

1.1.1. Ergonomics

PPE must be so designed and manufactured that in the foreseeable conditions of use for which it is intended the user can perform the risk related activity normally whilst enjoying appropriate protection of the highest possible level.

1.1.2. Levels and classes of protection

1.1.2.1. Highest level of protection possible

The optimum level of protection to be taken into account in the design is that beyond which the constraints by the wearing of the PPE would prevent its effective use during the period of exposure to the risk or normal performance of the activity.

1.1.2.2. Classes of protection appropriate to different levels of risk

Where differing foreseeable conditions of use are such that several levels of the same risk can be distinguished, appropriate classes of protection must be taken into account in the design of the PPE.

1.2. Innocuousness of PPE

1.2.1. Absence of risks and other inherent nuisance factors

PPE must be so designed and manufactured as to preclude risks and other nuisance factors under foreseeable conditions of use.

1.2.1.1. Suitable constituent materials

The materials of which the PPE is made, including any of their possible decomposition products, must not adversely affect the health or safety of users.

1.2.1.2. Satisfactory surface condition of all PPE parts in contact with the user

Any part of the PPE that is in contact or is liable to come into contact with the user when the PPE is worn must be free of rough surfaces, sharp edges, sharp points and the like which could cause excessive irritation or injuries

1.2.1.3. Maximum permissible user impediment

Any impediment caused by PPE to movements to be made, postures to be adopted and sensory perception must be minimized; nor must PPE cause movements which endanger the user or other persons.

1.3. Comfort and effectiveness

1.3.1. Adaptation of PPE to user morphology

PPE must be designed and manufactured in such a way as to facilitate its correct positioning on the user and to remain in place for the foreseeable period of use, bearing in mind ambient factors, the actions to be carried out and the postures to be adopted. For this purpose, it must be possible to adapt the PPE to fit the morphology of the user by all appropriate means, such as adequate adjustment and attachment systems or the provision of an adequate range of sizes.

1.3.2. Lightness and design strength

PPE must be as light as possible without prejudicing design strength and efficiency.

Apart from the specific additional requirements which they must satisfy in order to provide adequate protection against the risks in question (see 3), PPE must be capable of withstanding the effects of ambient phenomena inherent under the foreseeable conditions of use

1.4. Information supplied by the manufacturer

The notes that must be drawn up by the former and supplied when PPE is placed on the market must contain all relevant information on:

- a) In addition to the name and address of the manufacturer and/or his authorized representative established in the Community
- b) Storage, use, cleaning, maintenance, servicing and disinfection, cleaning, maintenance or disinfectant protection recommended by manufacturers must have no adverse effect on PPE or users when applied in accordance with the relevant instructions;
- c) Performance as recorded during technical tests to check the levels or classes of protection provided by the PPE in question;
- d) Suitable PPE accessories and the characteristics of appropriate spare parts;
- e) The classes of protection appropriate to different levels of risk and the corresponding limits of use;
- f) The obsolescence deadline or period of obsolescence of PPE or certain of its components;
- g) The type of packaging suitable for transport;
- h) The significance of any markings (see 2.12)
- i) Where appropriate the references of the Directives applied in accordance with Article 5(6) (b);
- j) The name, address and identification number of the notified body involved in the design stage of the PPE

These notes, which must be precise and comprehensible, must be provided at least in the official language(s) of the member state of destination





2. ADDITIONAL REQUIREMENTS COMMON TO SEVERAL CLASSES OR TYPES OF PPE

2.1. PPE incorporating adjustment systems

If PPE incorporates adjustment systems, the latter must be designed and manufactured so that, after adjustment, they do not become undone unintentionally in the foreseeable conditions of use.

2.3. PPE for the face, eyes and respiratory system

Any restriction of the user's face, eyes, field of vision or respiratory system by the PPE shall be minimised.

The screens for those types of PPE must have a degree of optical neutrality that is compatible with the degree of precision and the duration of the activities of the user.

If necessary, such PPE must be treated or provided with means to prevent misting-up.

Models of PPE intended for users requiring sight correction must be compatible with the wearing of spectacles or contact lenses.

2.4. PPE subject to ageing

If it is known that the design performance of new PPE may be significantly affected by ageing, the month and year of manufacture and/or, if possible, the month and year of obsolescence must be indelibly and unambiguously marked on each item of PPE placed on the market and on its packaging.

If the manufacturer is unable to give an undertaking with regard to the useful life of the PPE, his instructions must provide all the information necessary to enable the purchaser or user to establish a reasonable obsolescence month and year, taking into account the quality level of the model and the effective conditions of storage, use, cleaning, servicing and maintenance.

Where appreciable and rapid deterioration in PPE performance is likely to be caused by ageing resulting from the periodic use of a cleaning process recommended by the manufacturer, the latter must, if possible, affix a marking to each item of PPE placed on the market indicating the maximum number of cleaning operations that may be carried out before the equipment needs to be inspected or discarded. Where such a marking is not affixed, the manufacturer must give that information in his instructions.

2.6. PPE for use in potentially explosive atmospheres

PPE intended for use in potentially explosive atmospheres must be designed and manufactured in such a way that it cannot be the source of an electric, electrostatic or impact-induced arc or spark likely to cause an explosive mixture to ignite.

2.8. PPE for intervention in very dangerous situations

The instructions supplied by the manufacturer with PPE for intervention in very dangerous situations must include, in particular, data intended for competent, trained persons who are qualified to interpret them and ensure their application by the user.

The instructions must also describe the procedure to be adopted in order to verify that PPE is correctly adjusted and functional when worn by the user.

Where PPE incorporates an alarm which is activated in the absence of the level of protection normally provided, the alarm must be designed and placed so that it can be perceived by the user in the foreseeable conditions of use.

2.9. PPE incorporating components which can be adjusted or removed by the user

Where PPE incorporates components which can be attached, adjusted or removed by the user for replacement purposes, such components must be designed and manufactured so that they can be easily attached, adjusted and removed without tools.

2.12. PPE bearing one or more identification or recognition marks directly or indirectly relating to health and safety

The identification or recognition marks directly or indirectly relating to health and safety affixed to these types or classes of must preferably take the form of harmonized pictograms or ideograms and must remain perfectly legible throughout the foreseeable useful life of the PPE. In addition, these marks must be complete, precise and comprehensible so as to prevent any misinterpretation; in particular, where such marks incorporate words or sentences, the latter must appear in the official language(s) of the Member State where the equipment is to be used.

If PPE (or a PPE component) is too small to allow all or part of the necessary marking to be affixed, the relevant information must be mentioned on the packing and in the manufacturer's notes.

3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS

3.10.2. Protection against cutaneous and ocular contact

PPE intended to prevent the surface contact of all or part of the body with substances and mixtures which are hazardous to health or with harmful biological agents must be capable of preventing the penetration or permeation of such substances and mixtures and agents through the protective integument under the foreseeable conditions of use for which the PPE is intended.

To this end, the constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure, as far as possible, complete leak-tightness, which will allow where necessary prolonged daily use or, failing this, limited leak-tightness necessitating a restriction of the period of wear.

Where, by virtue of their nature and the foreseeable conditions of their use, certain substances and mixtures which are hazardous to health or harmful biological agents possess high penetrative power which limits the duration of the protection provided by the PPE in question, the latter must be subjected to standard tests with a view to their classification on the basis of their performance. PPE which is considered to be in conformity with the test specifications must bear a marking indicating, in particular, the names or, in the absence of the names, the codes of the substances used in the tests and the corresponding standard period of protection. The manufacturer's instructions must also contain, in particular, an explanation of the codes (if necessary), a detailed description of the standard tests and all appropriate information for the determination of the maximum permissible period of wear under the different foreseeable conditions of use.



Technical Assessment of EN 149: 2001 + A1: 2009 Standard and other Standards it refers to, Clauses Corresponding to the (EU) 2016/425 Directive

Conforming to EN 149:2001 + A1:2009 Standard Requirements

Article 5	Classification: Particle Filtering Half Mask Total Inward Leakage Classification – FFP2																																																																																																																														
Article 7.4	Packing: Particle filtering half masks are packaged to protect them from contamination before use and with cardboard boxes to prevent mechanical damage.																																																																																																																														
Article 7.5	Material: Materials used in particle filtering half masks, according to the simulated wearing treatment and temperature conditioning reports; It is understood withstand handling and wear over the period for which the particle filtering half mask is designed to be used suffered mechanical failure of the facepiece or straps, any material from the filter media released by the air flow through the filter has not constitute a hazard or nuisance for the wearer. <i>The model have colored ones manufactured by use of colored spunbound fabrics in the most outer layer of the mask, with the earloops as well. Based on the test results in the test report of SGS (Report numbers CANML2014109401 (Light Blue), CANML2014108401 (Black), CANML2014108601 (Grey), CANML2014108201 (Purple), CANML2014108901 (Green), CANML2014108801 (Orange), CANML2014108301 (Rose), CANML2014108301 (Deep Blue) and CANML2014108701 (Yellow) - prepared by SGS-CSIC Standards Technical Services Co., Ltd Guangzhou Branch SDS (Safety Data Sheet) reports. Based on the results the colored materials (spunbound fabric) used in the most outer layer of the mask is considered to be safe for use on the mask. Annexed sample photos of the colored masks. The material properties for both sizes (Standard and Medium are same).</i>																																																																																																																														
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Article 7.7	Practical Performance : <table border="1" style="width: 100%;"> <thead> <tr> <th>Assessed Elements</th> <th>Positive</th> <th>Negative</th> <th>Requirements in accordance with EN 149:2001 + A1:2009 and Result</th> </tr> </thead> <tbody> <tr> <td>1.The face piece fitting</td> <td>2</td> <td>0</td> <td rowspan="6">Positive results are obtained from the performance tests related to the implementation under real conditions, applied with the compatibility with skin evaluation (7.10). No imperfections</td> </tr> <tr> <td>2.Head harness comfort</td> <td>2</td> <td>0</td> </tr> <tr> <td>3.Security of fastenings</td> <td>2</td> <td>0</td> </tr> <tr> <td>4.Speech clearness</td> <td>2</td> <td>0</td> </tr> <tr> <td>5.Field of vision</td> <td>2</td> <td>0</td> </tr> <tr> <td>6.Materials compathibility with skin</td> <td>10</td> <td>0</td> </tr> </tbody> </table> <p>Conditioning : (A.R.) As Received, original</p>	Assessed Elements	Positive	Negative	Requirements in accordance with EN 149:2001 + A1:2009 and Result	1.The face piece fitting	2	0	Positive results are obtained from the performance tests related to the implementation under real conditions, applied with the compatibility with skin evaluation (7.10). No imperfections	2.Head harness comfort	2	0	3.Security of fastenings	2	0	4.Speech clearness	2	0	5.Field of vision	2	0	6.Materials compathibility with skin	10	0																																																																																																							
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Article 7.9.1	Total Inward Leakage: (Applied only for standard size) <table border="1" style="width: 100%;"> <thead> <tr> <th>Test Subject</th> <th>No of sample</th> <th>Condition</th> <th>1.Walk</th> <th>Head left/right</th> <th>Head up/down</th> <th>Speech</th> <th>2. Walk</th> <th>Average</th> </tr> </thead> <tbody> <tr><td>1</td><td>31</td><td>A.R</td><td>6.4</td><td>5.47</td><td>4.15</td><td>6.13</td><td>6.79</td><td>5.87</td></tr> <tr><td>2</td><td>32</td><td>A.R</td><td>6.53</td><td>4.45</td><td>6.17</td><td>7.29</td><td>7.45</td><td>6.38</td></tr> <tr><td>3</td><td>33</td><td>A.R</td><td>7.36</td><td>6.92</td><td>7.1</td><td>6.19</td><td>7.12</td><td>6.94</td></tr> <tr><td>4</td><td>34</td><td>A.R</td><td>6.33</td><td>5.24</td><td>7.32</td><td>6.26</td><td>7.4</td><td>6.51</td></tr> <tr><td>5</td><td>35</td><td>A.R</td><td>6.81</td><td>6.41</td><td>7.5</td><td>6.12</td><td>8.22</td><td>7.01</td></tr> <tr><td>6</td><td>16</td><td>T.C</td><td>5.63</td><td>7.45</td><td>6.75</td><td>7.21</td><td>6.2</td><td>6.65</td></tr> <tr><td>7</td><td>17</td><td>T.C</td><td>6.83</td><td>7.8</td><td>7.61</td><td>6.29</td><td>7.32</td><td>7.17</td></tr> <tr><td>8</td><td>18</td><td>T.C</td><td>7.69</td><td>7.9</td><td>8.96</td><td>8.28</td><td>8.19</td><td>8.2</td></tr> <tr><td>9</td><td>19</td><td>T.C</td><td>7.58</td><td>8.19</td><td>7.37</td><td>7.6</td><td>9.2</td><td>7.99</td></tr> <tr><td>10</td><td>20</td><td>T.C</td><td>7.57</td><td>7.41</td><td>7.42</td><td>7.76</td><td>8.87</td><td>7.81</td></tr> <tr><td colspan="3">Average</td><td>6.88</td><td>6.86</td><td>7.04</td><td>6.91</td><td>7.68</td><td>7.05</td></tr> <tr><td colspan="3">Min</td><td>5.63</td><td>4.45</td><td>4.15</td><td>6.12</td><td>6.2</td><td>5.87</td></tr> <tr><td colspan="3">Max</td><td>7.69</td><td>8.19</td><td>8.96</td><td>8.28</td><td>9.2</td><td>8.2</td></tr> </tbody> </table> <p>Conditioning : (A.R.) As Received, original (T.C.) Temperature conditioning</p> <p>Results P (%) Leakage Value</p> <p>It was reported that: All 50 exercise measurement results are smaller or equal to 11%, According to the results maximum measurement is 8,96 %. At least 9 of 10 individual's arithmetic mean is smaller or equal to 8%, According to the results the means for 10 subject varies between 5,87 % to 8,2 %.</p> <p>According to the reported results, the product meets the limits for FFP1 and FFP2 classification.</p>	Test Subject	No of sample	Condition	1.Walk	Head left/right	Head up/down	Speech	2. Walk	Average	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	6.83	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	Average			6.88	6.86	7.04	6.91	7.68	7.05	Min			5.63	4.45	4.15	6.12	6.2	5.87	Max			7.69	8.19	8.96	8.28	9.2	8.2
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Article 7.9.2

Penetration of filter material: Sodium Chloride Testing

Standard Size

Condition	No. of Sample	Sodium Chloride Testing 95 L/min max (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	-	3,65	FFP1 ≤ 20 %	Filtering half masks fulfill the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in range of the first and second protection class. FFP1, FFP2
(A.R.)	-	4,03		
(A.R.)	-	5,07		
(S.W.)	-	2,70	FFP2 ≤ 6 %	
(S.W.)	-	4,06		
(S.W.)	-	5,10	FFP3 ≤ 1 %	
(M.S. T.C.)	-	2,68		
(M.S. T.C.)	-	4,06		
(M.S. T.C.)	-	5,09		

95 L/min = 1,6 dm³.m⁻³

Medium Size

Condition	No. of Sample	Sodium Chloride Testing 95 L/min max (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	-	0,55	FFP1 ≤ 20 %	Filtering half masks fulfill the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in range of the first and second protection class. FFP1, FFP2
(A.R.)	-	0,83		
(A.R.)	-	0,58		
(S.W.)	-	1,70	FFP2 ≤ 6 %	
(S.W.)	-	1,28		
(S.W.)	-	0,58	FFP3 ≤ 1 %	
(M.S. T.C.)	-	1,03		
(M.S. T.C.)	-	1,34		
(M.S. T.C.)	-	1,52		

95 L/min = 1,6 dm³.m⁻³

Conditioning : (M.S.) Mechanical Strength
(T.C.) Temperature Conditioning
(A.R.) As Received, original
(S.W.) Simulated wearing treatment

Both sizes of the model complies with the FFP2 requirements

Article 7.9.2

Penetration of filter material: Paraffin Oil Testing

Standard Size

Condition	No. of Sample	Paraffin Oil Testing 95 L/min max (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	-	3,97	FFP1 ≤ 20 %	Filtering half masks fulfill the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in range of the first and second protection class. FFP1, FFP2
(A.R.)	-	3,18		
(A.R.)	-	4,58		
(S.W.)	-	4,01	FFP2 ≤ 6 %	
(S.W.)	-	3,20		
(S.W.)	-	4,61	FFP3 ≤ 1 %	
(M.S. T.C.)	-	3,99		
(M.S. T.C.)	-	3,21		
(M.S. T.C.)	-	4,63		

95 L/min = 1,6 dm³.m⁻³

Medium Size

Condition	No. of Sample	Paraffin Oil Testing 95 L/min max (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	-	1,24	FFP1 ≤ 20 %	Filtering half masks fulfill the requirements of the standard EN EN 149:2001 + A1:2009 given in 7.9.2 in range of the first and second protection class. FFP1, FFP2
(A.R.)	-	1,63		
(A.R.)	-	1,49		
(S.W.)	-	1,68	FFP2 ≤ 6 %	
(S.W.)	-	1,65		
(S.W.)	-	1,47	FFP3 ≤ 1 %	
(M.S. T.C.)	-	1,71		
(M.S. T.C.)	-	2,98		
(M.S. T.C.)	-	1,76		

Conditioning : (M.S.) Mechanical Strength
(T.C.) Temperature Conditioning
(A.R.) As Received, original
(S.W.) Simulated wearing treatment

Both sizes of the model complies with the FFP2 requirements

Article 7.10

Compatibility with skin: In Practical Performance report, the likelihood of mask materials in contact with the skin causing irritation or other adverse effect on health was not reported.





Article 7.11	Flammability :						
	Condition	No. of Sample	Visual inspection	Requirements in accordance with EN 149:2001 + A1:2009	Result		
	(A.R.)	-	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 fulfill requirements of the standard		
	(A.R.)	-	2,08				
	(T.C.)	-	2,19				
	(T.C.)	-	2,14				
Conditioning : (A.R.) As Received, original (T.C.) Temperature Conditioning							
Article 7.12	Carbon dioxide content of the inhalation air:						
	Condition	No. of Sample	CO ₂ content of the inhalation air [%] by volume	An average CO ₂ content of the inhalation air	Requirements in accordance with EN 149:2001 + A1:2009	Result	
	(A.R.)	-	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 fulfill requirements of the standard	
	(A.R.)	-	0,64				
(A.R.)	-	0,59					
Conditioning : (A.R.) As Received, original							
Article 7.13	Head harness: In Practical Performance report, No adverse effects have been reported for holding the mask of the head harness firmly in position, for total inward leakage properties. Tested on samples 10 samples.						
Article 7.14	Field of vision: In Practical Performance report, no adverse effects were reported for the field of vision features.						
Article 7.16	Breathing Resistance: Inhalation						
	Standard Size						
	Inhalation Resistance (mbar)						
	Condition	No. of Sample	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	Result
	(A.R.)	42	0,36	FFP1 ≤ 0,6	1,21	FFP1 ≤ 2,1	Passed
	(A.R.)	43	0,38		1,25		
	(A.R.)	44	0,37		1,23		
	(S.W.)	7	0,38	FFP2 ≤ 0,7	1,23	FFP2 ≤ 2,4	
	(S.W.)	8	0,40		1,27		
	(S.W.)	9	0,39		1,26		
	(T.C.)	23	0,37	FFP3 ≤ 1,0	1,25	FFP3 ≤ 3,0	
	(T.C.)	24	0,38		1,28		
	(T.C.)	25	0,38		1,29		
	Medium Size						
Inhalation Resistance (mbar)							
Condition	No. of Sample	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	Result	
(A.R.)	42	0,58	FFP1 ≤ 0,6	1,68	FFP1 ≤ 2,1	Passed	
(A.R.)	43	0,51		1,43			
(A.R.)	44	0,55		1,50			
(S.W.)	7	0,53	FFP2 ≤ 0,7	1,67	FFP2 ≤ 2,4		
(S.W.)	8	0,55		1,69			
(S.W.)	9	0,60		1,73			
(T.C.)	23	0,62	FFP3 ≤ 1,0	1,76	FFP3 ≤ 3,0		
(T.C.)	24	0,59		1,68			
(T.C.)	25	0,57		1,49			
The overall evaluation in the figures gathered for 9 different samples 3 as received, 3 with temperature conditioning and 3 temperature + mechanical conditioning complies with the limits given in the standard for FFP2 and FFP3 classes. This is valid for inhalation results for 30 L/min, 95 L/min and exhalation at 160 L/min.							
Passed.							





Breathing Resistance: Exhalation									
Standard Size									
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	160 l/min	2,18	2,20	2,21	2,20	2,21	FFP1 ≤ 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	FFP2 ≤ 3,0	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	FFP3 ≤ 3,0	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

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

The overall evaluation in the figures gathered for 9 different samples (3 as received, 3 with temperature conditioning and 3 temperature + mechanical conditioning, of each size (standard and medium) complies with the limits given in the standard for FFP1, FFP2 and FFP3 classes. This is valid for inhalation results for 30 L/min, 95 L/min and exhalation at 160 L/min.

Passed.

Article 7.17.2	Clogging: This test is not applied to Particle Filtering Half Mask which is not reusable. <i>(For single shift use devices, the clogging test is optional test. For reusable devices test is mandatory.)</i>
Article 7.17.3	Penetration of filter material: This test is not applied to Particle Filtering Half Mask which is not reusable.
Article 7.18	Demountable Parts: There are no demountable parts on the product.
Article 9	Marking – Packaging: Manufacturer expected to put necessary information (reference to standard, user instructions etc) markings as defined on the product and its packaging templates. <i>The tested samples as medium size did not have the correct model name CAD-01 outside, the other expectations of the standard were in conformance.</i>
Article 10	Information to be supplied by the manufacturer: In each of the smallest commercially available packaging of the product, implementation (installation instruction) pre-use controls, warning and usage limitations, storage and meanings of symbols / pictograms are defined in the technical file templates.





Colored samples of the Masks



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