Mascarilla FFP2 - Embolsadas individualmente caja de 10 unidades

Características técnicas:

- Cumple con la normativa EN 149:2001+A1:2009
- Eficiencia de filtrado >95%
- Certificado CE 2163. Las mascarillas cuentan con certificado CE para los productos de la categoría III. Las mascarillas han superado con éxito los tests que se han llevado a cabo y cumple con los requisitos establecidos en el Reglamento sobre equipos de protección personal (UE) 2016/425 y normas garantizadas por evaluaciones basadas en el anexo 7 (módulo C) o el anexo 8 (módulo d).
- Diseño de cinco capas: Agradable para la piel. El exterior está elaborado con tela no tejida, dos capas de tela fundida envuelta con capa de relleno
- Filtro medio de mayor eficiencia para la más alta protección contra partículas por encima de los requisitos estándar
- Elástico de sujeción que ofrece un plus de durabilidad a la mascarilla.
- Permite la comunicación.
- Puente nasal interior de alta estabilidad.
- Probada su eficacia en laboratorios. Este certificado de cumplimiento se ha otorgado en función de los resultados de las pruebas realizadas por la empresa Guangdong YiDao Medical Technology Co.,
- Medios filtrantes de alto rendimiento con baja resistencia a la respiración.
- Excepcional comodidad y ajuste de la mascarilla para los usuarios.

Calle Constitución, 124. 28946. Fuenlabrada (Madrid) 91 632 77 40 tienda@fisaude.com

RESPIRATORY HEALTH
FFP2 Mask

广东医道医疗科技有限公司

Guangdong Yidao Medical Technology Co., Ltd

公司简介
Company Profile

Guangdong YiDao Medical Technology Co., Ltd, our main products : Why choose us?

1: Real Europe CE with UNIVERSAL Certificate NB2163, test report EN149:2001+A1:2009, which include intact Module B and Module C2.

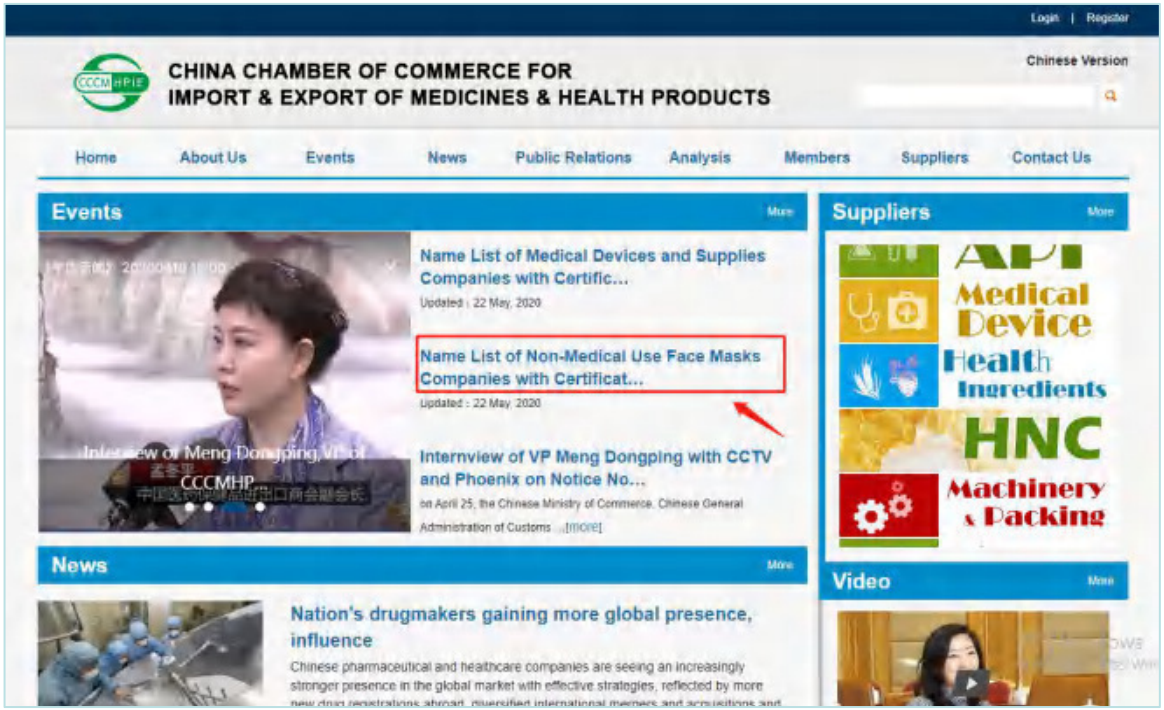
2: Qualified products made by factory which is authorized to export by China's Ministry of Commerce.

3: Output 3 million per day, delivery time very fast.

4: Door to door service is availble for us.

White List in CCCM

China Non Medical Mask White List, http://en.cccmhpie.org.cn



70	广东医道医疗科技有限公司 Guangdong Yidao Medical Technology Co., Ltd.	91441900MA54DTP095	CE

http://en.cccmhpie.org.cn/Web/Content.aspx?queryStr=w7x08q7x15x15o3w8w1vS9z8w7x1X10x16x0X10x16o3w8w1u9v1u9v4u9v1

CE证书
CE Certificate NB2163

UNIVERSAL

UNIVERSAL
CERTIFICATION
NB 2163

CERTIFICATE OF CONFORMANCE

Certificate Nr: 2163-PPE-639/01

Respiratory protective devices, filtering half masks to protect against particles manufactured by

Guangdong YIDAO Medical Technology Co., LTD.

at the following manufacturing site

Room 302, Building 2, No. 1, Lane 1, Xiju Road, Hengli, Dongguan City, Guangdong Province, P. R. CHINA

Continues to fulfil the requirements of

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

Based on the evaluation of test reports and internal quality control audit reports according to EN 149+A1:2009 and Personal Protective Equipment Regulation (EU) 2016/425 Annex VII (Module C2). This certificate implies that the manufactured products show below are in conformance with the approved EU Type Examination model and meets the requirements of the regulation. The details of compliance is given in technical report numbered **2163-PPE-640/01**

Product Definition

Model	Class	EU Type Examination Certificate		
		Serial Nr.	Date	Notified Body NB Nr.
YD-002	FFP2	2163-PPE-639	28/04/2020	2163

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.**
- Taking all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type examination certificate.

This certificate is issued on **28/04/2020** and will be valid for one year, until **27/04/2021** if the manufacturer makes no major change in the product designs and manufacturing processes affecting the product performance on the essential health and safety requirement.

CE 2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

The validity of this certificate can be verified online.

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CERTIFICATION
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EU TYPE EXAMINATION CERTIFICATE

Certificate Nr: 2163-PPE-639

Respiratory protective devices, filtering half masks to protect against particles manufactured by

Guangdong YIDAO Medical Technology Co., LTD.

Room 302, Building 2, No. 1, Lane 1, Xiju Road, Hengli, Dongguan City, Guangdong Province, P. R. 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. The details of essential requirement compliance is given in technical report numbered **2163-PPE-640.**

Product Definition

Brand Name: YPHD **Model:** YD-002

Filtering half mask

Total Inwards Leakage: Class – FFP2

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 **28/04/2020** and will be valid for 5 years if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.

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7.11 Flammability (EN 149:2001 + A1:2009 clause 8.6)	
See tested reference number FT-001	*Passed*
7.12 Carbon dioxide content of the inhalation air (EN 149:2001 + A1:2009 clause 8.7)	
See tested reference number CDT-001	*Passed*
7.13 Head harness (EN 149:2001 + A1:2009 clause 8.4, 8.5)	
The head harness was designed to allow the particle filtering half-mask to be donned and removed easily during limited practical performance and total inward leakage testing.	*Passed*
The head harness was adjustable and there were no adverse comments regarding security following limited practical performance and total inward leakage testing.	*Passed*
The product satisfied the total inward leakage requirements.	*Passed*
7.14 Field of vision (EN 149:2001 + A1:2009 clause 8.4)	
There were no adverse comments following practical performance tests.	*Passed*
7.15 Exhalation Valve (EN 149:2001 + A1:2009 clause 8.2, 8.3.4, 8.8, 8.9.1)	
Not applicable	*N/A*
7.16 Breathing Resistance (EN 149:2001 + A1:2009 clause 8.9)	
See tested reference number BRT-001	*Passed*
7.17 Clogging (EN 149:2001 + A1:2009 clause 8.9, 8.10)	
This is optional test and not desired by client.	*NAs*
7.18 Demountable Parts (EN 149:2001 + A1:2009 clause 8.2)	
No demountable parts	*N/A*
8.3 Conditioning	
See tested reference number CS-001	*Passed*

Passed	*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.*

Conclusion:

Model	*Recommendation Level*
YD-002	FFP2 NR

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Test Standard: EN 149:2001+A1:2009 / EN 13274-5:2001
Name of tests: Conditioning of Samples
Reference no: CS-001

Simulated wearing treatment
Conditioning by simulated wearing treatment has been carried out by the following process. 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.

In order to prevent excess water spilling out of the dummy's mouth and contaminating the particle filtering half mask the head has been inclined so that the water runs away from the mouth and is collected in a trap. The breathing machine was brought into operation, the saturator switched on and the apparatus allowed to stabilize. The particle filtering half mask under test has then been mounted on the dummy head. During the last time at approximately 20 min intervals the particle filtering half mask has been completely removed from the dummy head and refitted such that during the test period it is fitted ten times to the dummy head.

Temperature conditioning
Unless otherwise specified, the ambient temperature for testing has been between 18 °C and 32 °C and the temperature shall has been adjust to an accuracy of ±1 °C.

In order to ensure that there is no thermal shock during the conditioning of the specimens, the temperature gradient has been less than 2 °C/min between phases at different temperatures, or between the beginning and the end of a thermal cycle.

Expose the particle filtering half masks to the following thermal cycle:
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.

Mechanical strength
The apparatus consists of a steel case (K) which is fixed on a vertically moving piston (S), capable of being lifted up 20 mm by a rotating cam (N) and dropping down onto a steel plate (P) under its own mass as the cam rotates. The mass of the steel case shall be more than 10 kg. The weight of the steel plate onto which the steel case falls should be (at least) 10 times the weight of the steel case. This may be achieved by bolting the base plate to a hard solid floor.

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

No	*Conditioning Area*	*Samples Number*
1	Simulated wearing treatment	1-2-3-4-5-6 (As Received)
2	Temperature conditioning	7-8-9-10-11-12 (Sample after test of Mechanical Strength)
		13-14-15-16-17-18-19-20-21-22 (As Received)
3	Mechanical strength	7-8-9-10-11-12 (As Received)

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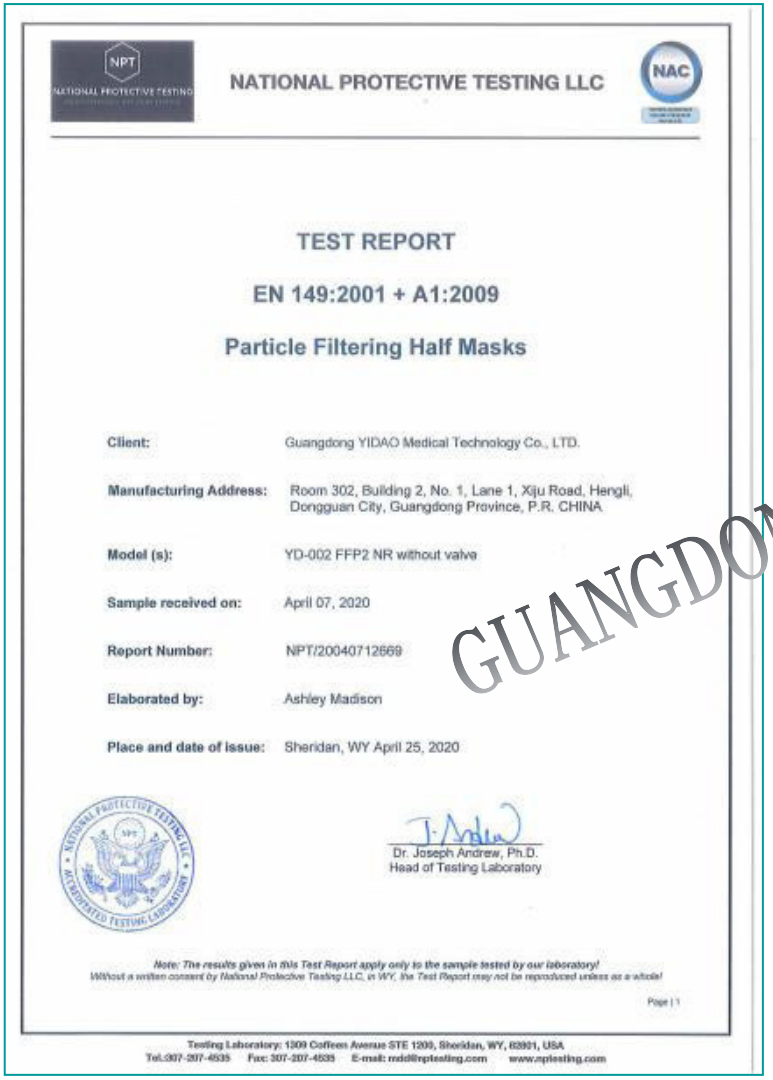

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TEST REPORT

EN 149:2001 + A1:2009

Particle Filtering Half Masks

Client:	Guangdong YIDAO Medical Technology Co., LTD.
Manufacturing Address:	Room 302, Building 2, No. 1, Lane 1, Xiju Road, Hengli, Dongguan City, Guangdong Province, P.R. CHINA
Model (s):	YD-002 FFP2 NR without valve
Sample received on:	April 07, 2020
Report Number:	NPT/20040712669
Elaborated by:	Ashley Madison
Place and date of issue:	Sheridan, WY April 25, 2020

Dr. Joseph Andrew, Ph.D.
Head of Testing Laboratory

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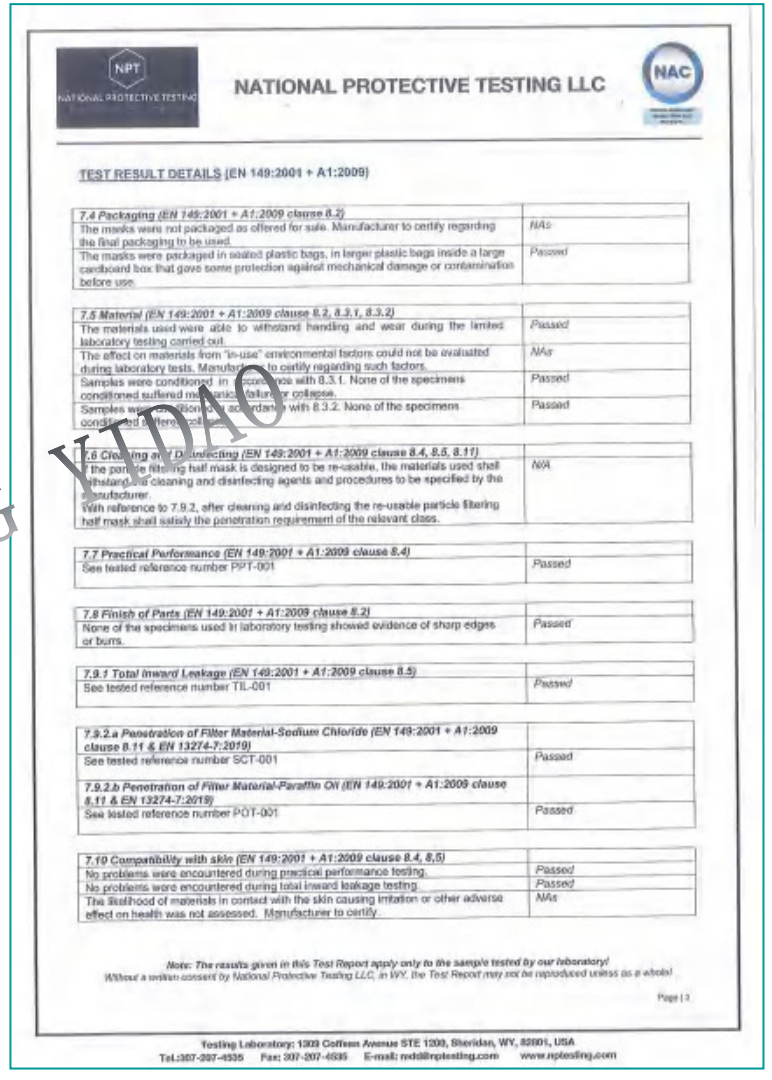

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TEST RESULT DETAILS (EN 149:2001 + A1:2009)

7.4 Packaging (EN 149:2001 + A1:2009 clause 8.2)	
The masks were not packaged as offered for sale. Manufacturer to certify regarding the final packaging to be used.	NAs
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.	Passed

7.5 Material (EN 149:2001 + A1:2009 clause 8.2, 8.3.1, 8.3.2)	
The materials used were able to withstand handling and wear during the limited laboratory testing carried out.	Passed
The effect on materials from "in-use" environmental factors could not be evaluated during laboratory tests. Manufacturer to certify regarding such factors.	NAs
Samples were conditioned in accordance with 8.3.1. None of the specimens conditioned suffered mechanical failure or collapse.	Passed
Samples were conditioned in accordance with 8.3.2. None of the specimens conditioned suffered collapse.	Passed

7.6 Cleaning and Disinfecting (EN 149:2001 + A1:2009 clause 8.4, 8.5, 8.11)	
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

7.7 Practical Performance (EN 149:2001 + A1:2009 clause 8.4)	
See tested reference number PPT-001	Passed

7.8 Finish of Parts (EN 149:2001 + A1:2009 clause 8.2)	
None of the specimens used in laboratory testing showed evidence of sharp edges or burrs.	Passed

7.9.1 Total Inward Leakage (EN 149:2001 + A1:2009 clause 8.5)	
See tested reference number TIL-001	Passed

7.9.2.a Penetration of Filter Material-Sodium Chloride (EN 149:2001 + A1:2009 clause 8.11 & EN 13274-7:2019)	
See tested reference number SCT-001	Passed
7.9.2.b Penetration of Filter Material-Paraffin Oil (EN 149:2001 + A1:2009 clause 8.11 & EN 13274-7:2019)	
See tested reference number POT-001	Passed

7.10 Compatibility with skin (EN 149:2001 + A1:2009 clause 8.4, 8.5)	
No problems were encountered during practical performance testing.	Passed
No problems were encountered during total inward leakage testing.	Passed
The likelihood of materials in contact with the skin causing irritation or other adverse effect on health was not assessed. Manufacturer to certify.	NAs

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Test Standard: EN 149:2001+A1:2009 / EN 13274-2:2001
Name of tests: Practical Performance Testing
Reference no: PPT-001

Test Purpose:
This test method is used to determine practical performance when its purpose is fitted by subjects during use in the simulated application, it subjectively evaluates certain features, characteristics and functions of the device that cannot be evaluated by experiments described in other standards.

Sampling method:
A total of two particle filtering half masks have been tested: two in the state as received.

Testing methods used:
A test method for determining practical performance in accordance with standard EN 13274-2:2001 + EN 149:2001 + A1:2009 clause 7.7/8.4

Test conditions:
The test has been carried out in a normally lit area with a temperature of 16 ° C to 32 ° C and a relative humidity of 30% to 80%. The actual temperature and humidity conditions and noise level have been recorded.

Test Principle:
A total of 2 particle filtering half masks have been tested: both as received. All tests have been carried out by two test subjects at ambient temperature and the test temperature and humidity have been recorded. Prior to the test there has been an examination to assure that the particle filtering half mask is in good working condition and that it can be used without hazard. For the test, persons have been selected who are familiar with using such or similar equipment.

Test Equipment:
A small basket (approximate volume = 8 l) with chippings or other suitable material from a hopper

Test Procedure:
General: During the tests the particle filtering half mask shall be subjectively assessed by the wearer and the test comments on the following shall be recorded: a) head harness comfort; b) security of fastenings; c) field of vision; d) any other comments reported by the wearer on request.

Walking test: The subjects wearing normal working clothes and wearing the particle filtering half mask, shall walk at a regular rate of 6 km/h on a level course. The test shall be continuous, without removal of the particle filtering half mask, for a period of 10 min.

Work simulation test: The particle filtering half mask shall be tested under conditions which can be expected during normal use. During this test the following activities shall be carried out in simulation of the practical use of the particle filtering half mask. The test shall be completed within a total working time of 20 min. The sequence of activities is at the discretion of the test house. The individual activities shall be arranged so that sufficient time is left for the comments prescribed.
a) walking on the level with headroom of (1,3 ± 0,2) m for 5 min;
b) crawling on the level with headroom of (0,70 ± 0,05) m for 5 min;
c) filling a small basket (see Figure 1, approximate volume = 8 l) with chippings or other suitable material from a hopper which stands 1,5 m high and has an opening at the bottom to allow the contents to be shovelled out and a further opening at the top where the basket full of chippings is returned. The subject shall stoop or kneel as he wishes and fill the basket with chippings. He shall then lift the basket and empty the contents back into the hopper. This shall be done 20 times in 10 min.

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

Number of sample: 39 (A.R), 40 (A.R)

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

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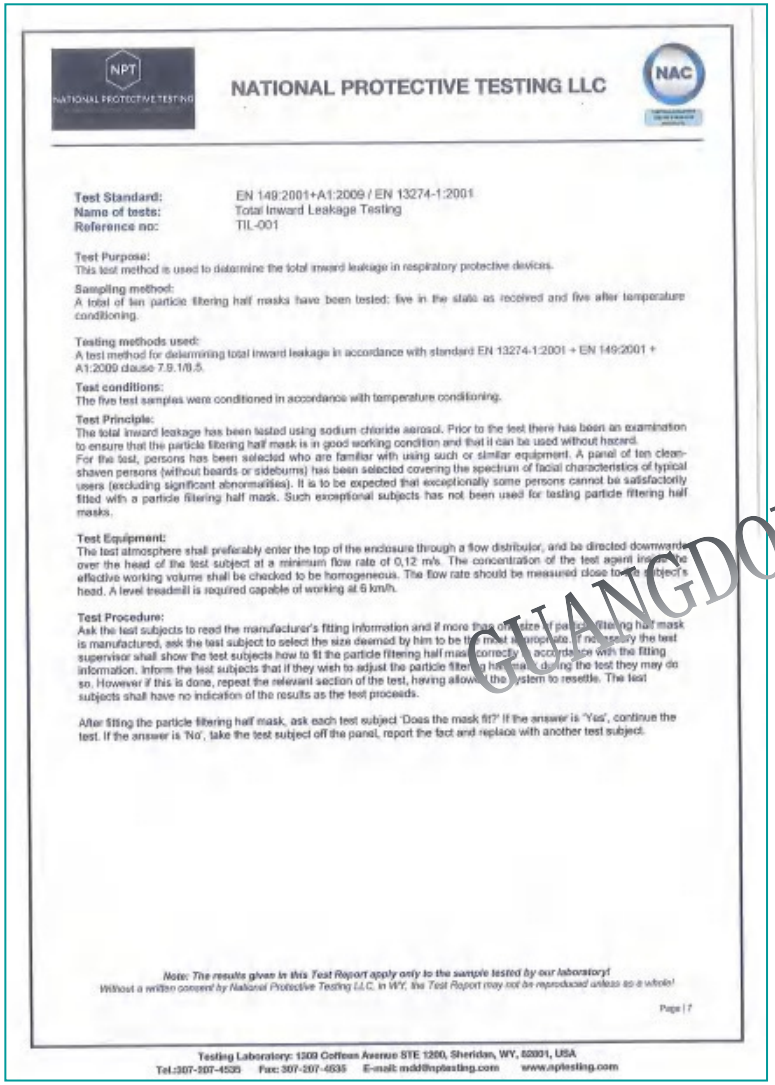

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Test Standard: EN 149:2001+A1:2009 / EN 13274-1:2001
Name of tests: Total Inward Leakage Testing
Reference no: TIL-001

Test Purpose:
This test method is used to determine the total inward leakage in respiratory protective devices.

Sampling method:
A total of ten particle filtering half masks have been tested: five in the state as received and five after temperature conditioning.

Testing methods used:
A test method for determining total inward leakage in accordance with standard EN 13274-1:2001 + EN 149:2001 + A1:2009 clause 7.9.1/8.5.

Test conditions:
The five test samples were conditioned in accordance with temperature conditioning.

Test Principle:
The total inward leakage has been tested using sodium chloride aerosol. Prior to the test there has been an examination to ensure that the particle filtering half mask is in good working condition and that it can be used without hazard.
For the test, persons has been selected who are familiar with using such or similar equipment. A panel of ten clean-shaven persons (without beards or sideburns) has been selected covering the spectrum of facial characteristics of typical users (excluding significant abnormalities). It is to be expected that exceptionally some persons cannot be satisfactorily fitted with a particle filtering half mask. Such exceptional subjects has not been used for testing particle filtering half masks.

Test Equipment:
The test atmosphere shall preferably enter the top of the enclosure through a flow distributor, and be directed downwards over the head of the test subject at a minimum flow rate of 0,12 m/s. The concentration of the test agent in the effective working volume shall be checked to be homogeneous. The flow rate should be measured close to the subject's head. A level treadmill is required capable of working at 6 km/h.

Test Procedure:
Ask the test subjects to read the manufacturer's fitting information and if more than one size of particle filtering half mask is manufactured, ask the test subject to select the size deemed by him to be the most appropriate. If necessary the test supervisor shall show the test subjects how to fit the particle filtering half mask correctly in accordance with the fitting information. Inform the test subjects that if they wish to adjust the particle filtering half mask during the test they may do so. However if this is done, repeat the relevant section of the test, having allowed the system to resettle. The test subjects shall have no indication of the results as the test proceeds.

After fitting the particle filtering half mask, ask each test subject 'Does the mask fit?' If the answer is 'Yes', continue the test. If the answer is 'No', take the test subject off the panel, report the fact and replace with another test subject.

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Test results:
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	32	A.R.	4,93	5,21	4,88	5,10	4,77	4,98
2	33	A.R.	4,96	5,32	4,89	5,41	4,79	5,07
3	34	A.R.	4,85	5,62	4,95	5,68	4,91	5,20
4	35	A.R.	4,77	5,56	4,75	5,30	4,66	5,01
5	36	A.R.	4,82	5,52	4,77	5,66	4,72	5,10
6	16	T.C.	5,11	5,41	5,11	5,34	5,10	5,21
7	17	T.C.	5,25	5,49	5,25	5,49	5,15	5,33
8	18	T.C.	5,29	4,32	5,16	5,34	5,16	5,05
9	19	T.C.	5,34	5,22	5,35	5,42	5,21	5,31
10	20	T.C.	5,24	5,32	5,37	5,38	5,26	5,31
Maximum permitted			All individual exercise results were not greater than 11 %					Not greater than 8%

Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity
at least 46 out of the 50 individual results shall be not greater than 25 % for FFP1 11 % for FFP2 5 % for FFP3 and at least 8 out of the 10 individual wearer means shall be not greater than 22 % for FFP1 8 % for FFP2 2 % for FFP3	Passed Filtering half masks fulfil requirements of the standard EN 149:2001 + A1:2009 given in 7.9.1 in range of the first, the second and the third protection class (FFP1, FFP2, FFP3)

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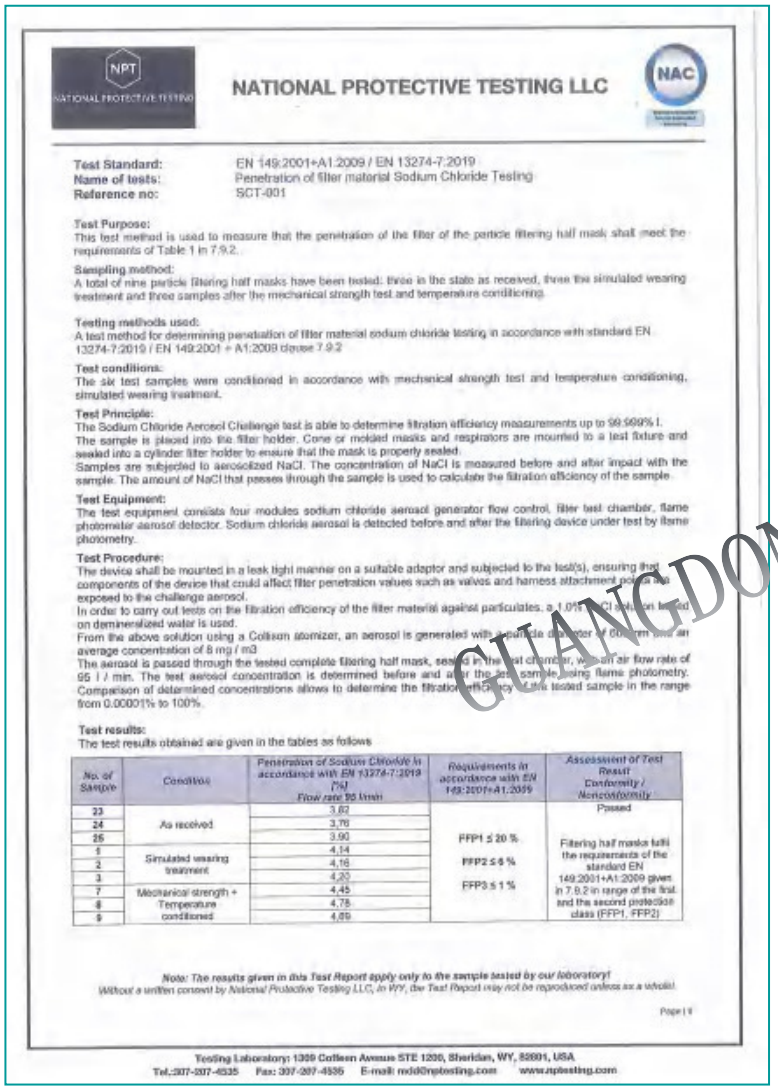

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Test Standard: EN 149:2001+A1:2009 / EN 13274-7:2019
Name of tests: Penetration of filter material Sodium Chloride Testing
Reference no: SCT-001

Test Purpose:
This test method is used to measure that the penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1 in 7.9.2.

Sampling method:
A total of nine particle filtering half masks have been tested: three in the state as received, three the simulated wearing treatment and three samples after the mechanical strength test and temperature conditioning.

Testing methods used:
A test method for determining penetration of filter material sodium chloride testing in accordance with standard EN 13274-7:2019 / EN 149:2001 + A1:2009 clause 7.9.2

Test conditions:
The six test samples were conditioned in accordance with mechanical strength test and temperature conditioning, simulated wearing treatment.

Test Principle:
The Sodium Chloride Aerosol Challenge test is able to determine filtration efficiency measurements up to 99.999% I.
The sample is placed into the filter holder. Cone or molded masks and respirators are mounted to a test fixture and sealed into a cylinder filter holder to ensure that the mask is properly sealed.
Samples are subjected to aerosolized NaCl. The concentration of NaCl is measured before and after impact with the sample. The amount of NaCl that passes through the sample is used to calculate the filtration efficiency of the sample.

Test Equipment:
The test equipment consists four modules sodium chloride aerosol generator flow control, filter test chamber, flame photometer aerosol detector. Sodium chloride aerosol is detected before and after the filtering device under test by flame photometry.

Test Procedure:
The device shall be mounted in a leak tight manner on a suitable adaptor and subjected to the test(s), ensuring that components of the device that could affect filter penetration values such as valves and harness attachment points are exposed to the challenge aerosol.
In order to carry out tests on the filtration efficiency of the filter material against particulates, a 1.0% NaCl solution is used on demineralized water is used.
From the above solution using a Collson atomizer, an aerosol is generated with a particle diameter of 0.6 mm and an average concentration of 8 mg / m3
The aerosol is passed through the tested complete filtering half mask, sealed in the test chamber, with an air flow rate of 95 l / min. The test aerosol concentration is determined before and after the test sample, using flame photometry. Comparison of determined concentrations allows to determine the filtration efficiency of the tested sample in the range from 0.00001% to 100%.

Test results:
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
23	As received	3,82	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 the second protection class (FFP1, FFP2)
24		3,76		
25		3,90		
1	Simulated wearing treatment	4,14		
2		4,16		
3		4,20		
7	Mechanical strength + Temperature conditioned	4,45		
8		4,78		
9		4,69		

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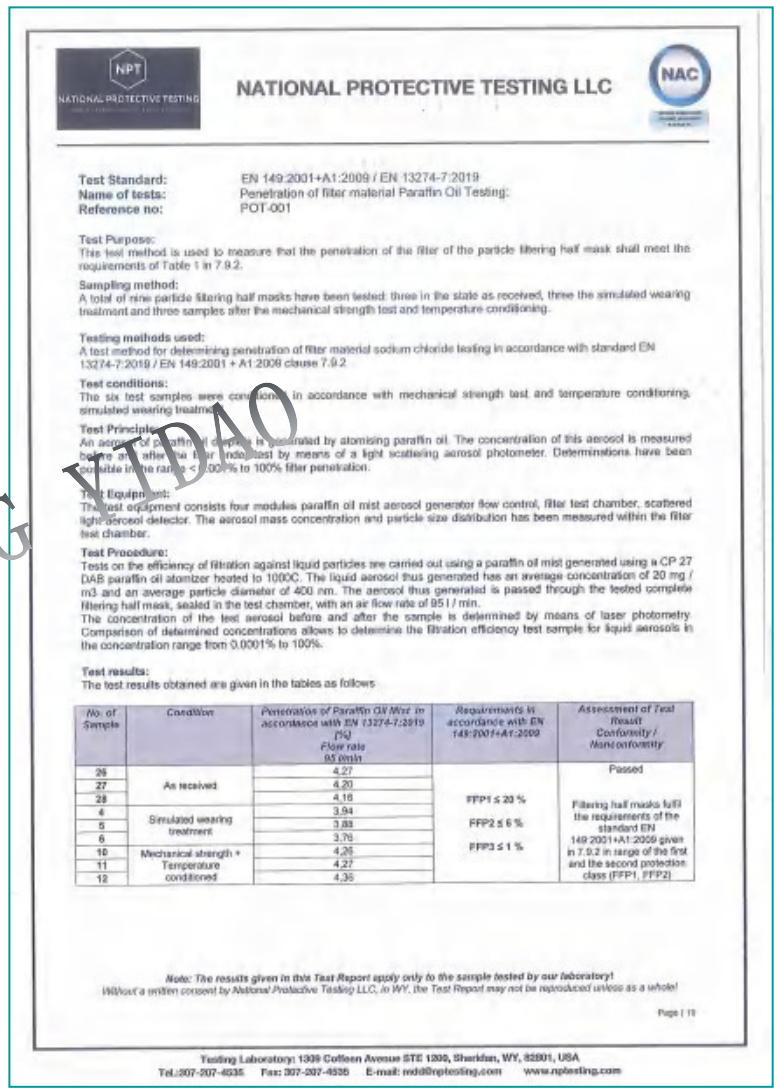

NATIONAL PROTECTIVE TESTING LLC

Test Standard: EN 149:2001+A1:2009 / EN 13274-7:2019
Name of tests: Penetration of filter material Paraffin Oil Testing:
Reference no: POT-001

Test Purpose:
This test method is used to measure that the penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1 in 7.9.2.

Sampling method:
A total of nine particle filtering half masks have been tested: three in the state as received, three the simulated wearing treatment and three samples after the mechanical strength test and temperature conditioning.

Testing methods used:
A test method for determining penetration of filter material sodium chloride testing in accordance with standard EN 13274-7:2019 / EN 149:2001 + A1:2009 clause 7.9.2

Test conditions:
The six test samples were conditioned in accordance with mechanical strength test and temperature conditioning, simulated wearing treatment.

Test Principle:
An aerosol of paraffin oil droplets is generated by atomising paraffin oil. The concentration of this aerosol is measured before and after the filter undertest by means of a light scattering aerosol photometer. Determinations have been possible in the range < 0.001% to 100% filter penetration.

Test Equipment:
The test equipment consists four modules paraffin oil mist aerosol generator flow control, filter test chamber, scattered light aerosol detector. The aerosol mass concentration and particle size distribution has been measured within the filter test chamber.

Test Procedure:
Tests on the efficiency of filtration against liquid particles are carried out using a paraffin oil mist generated using a CP 27 DAB paraffin oil atomizer heated to 1000C. The liquid aerosol thus generated has an average concentration of 20 mg / m3 and an average particle diameter of 400 nm. The aerosol thus generated is passed through the tested complete filtering half mask, sealed in the test chamber, with an air flow rate of 95 l / min.
The concentration of the test aerosol before and after the sample is determined by means of laser photometry. Comparison of determined concentrations allows to determine the filtration efficiency test sample for liquid aerosols in the concentration range from 0.0001% to 100%.

Test results:
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
26	As received	4,27	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 the second protection class (FFP1, FFP2)
27		4,20		
28		4,16		
4	Simulated wearing treatment	3,94		
5		3,88		
6		3,76		
10	Mechanical strength + Temperature conditioned	4,26		
11		4,27		
12		4,36		

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NATIONAL PROTECTIVE TESTING LLC

Test Standard: EN 149:2001+A1:2009 / EN 13274-4:2001
Name of tests: Flammability Testing
Reference no: FT-001

Test Purpose:
This test method is used to measure that the materials used in the device are not dangerous for the person using the device and do not possess highly flammable nature.

Sampling method:
A total of four particle filtering half masks have been tested: two in the state as received and two after temperature conditioning.

Testing methods used:
A test method for determining Flammability in accordance with standard EN 13274-4:2001 + EN 149:2001 + A1:2009 clause 7.11/8.6.

Test conditions:
The two test samples were conditioned in accordance with temperature conditioning.

Test Principle:
The filtering face pieces subjected to the test, are passed one by one through a flame with a temperature of 800°C +/- 50°C and at a speed of 8 cm/s. The respirators must not go on burning for more than 5 s after removal from the flame.

Test Equipment:
The test rig consists mainly of a propane cylinder with flow control device, pressure gauge, flash back arrester, specimen support, rotation motor with speed controller, and burner. The burner has been either be in accordance with 6.2 or with ISO 6941. The purity of the propane has been a minimum of 95 %.

Test Procedure:
The face piece is put on a metallic dummy head which is motorized such that it describes a horizontal circle with a linear speed, measured at the tip of the nose, of (60 ± 5) mm/s. The head is arranged to pass over a propane burner the position of which can be adjusted. By means of a suitable gauge, the distance between the top of the burner, and the lowest part of the face piece (when positioned directly over the burner) shall be set to (20 ± 2) mm.

With the head turned away from the area adjacent to the burner, the propane gas is turned on, the pressure adjusted to between 0,2 bar and 0,3 bar and the gas ignited. By means of a needle valve and fine adjustment on the supply pressure, the flame height had been set to (40 ± 4) mm. This is measured with a suitable gauge.

The temperature of the flame measured at a height of (20 ± 2) mm above the burner tip by means of a 1,5 mm diameter mineral insulated thermocouple probe, shall be (800 ± 50) °C. Failure to meet the temperature requirement indicates that a fault such as a partially blocked burner exists. This had been rectified before testing. The head is set in motion and the effect of passing the face piece once through the flame has been noted.

The test has been repeated to enable an assessment to be made of all materials on the exterior of the device. Any one component has been passed through the flame once only

Test results:
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
32	As received	1,4	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 EN 149:2001 + A1:2009 given in 7.1
33		1,3		
21	Temperature conditioned	1,2		
22		1,1		

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NATIONAL PROTECTIVE TESTING LLC

Test Standard: EN 149:2001+A1:2009 / EN 13274-6:2001
Name of tests: Carbon dioxide content of the inhalation air Testing
Reference no: COT-001

Test Purpose:
This test method is used to determine carbon dioxide content of the inhalation air.

Sampling method:
A total of three particle filtering half masks have been tested: all three in the state as received.

Testing methods used:
A test method for determining carbon dioxide content of the inhalation air in accordance with standard EN 13274-6:2001 + EN 149:2001 + A1:2009 clause 7.12/8.7.

Test conditions:
The atmosphere where the temperature is from 16 ° C to 32 ° C and the relative humidity is 20% to 85%.

Test Principle:
The device is attached to the Sheffield mannequin head / body as described in the device standard. In the case of complete hardware testing, an air supply is operated under the manufacturer's lowest conditions, unless otherwise specified in the relevant standard. Air containing carbon dioxide at a certain concentration is supplied from the respirator to the mannequin head / body at a given flow rate. The inhaled air is analysed for its carbon dioxide content.
The measured concentrations provide information on the assessment of the "dead volume" of the facial protective part rather than a direct measurement of the carbon dioxide level in the inhaled air.

Test Equipment:
The test rig consists Breathing apparatus, Auxiliary lung, Solenoid valve, Sheffield Mannequin head, Non-return valve, Sampling pipe for breathing air, Flow meter, Carbon dioxide absorber, Balancer, Carbon dioxide supply, Carbon dioxide analyzer

Test Procedure:
The apparatus subjects the particle filtering half mask to a respiration cycle by the breathing machine. For this test the particle filtering half mask has been fitted securely in a leak-tight manner but without deformation to a Sheffield dummy head. Air has been supplied to it from a breathing machine adjusted to 25 cycles/min and 2,0 l/stroke and the exhaled air has a carbon dioxide content of 5 % by volume. If the design of the test equipment causes a CO2 build-up a CO2 absorber has been used in the inhalation branch between solenoid valve and breathing machine. The CO2 is fed into the breathing machine via a control valve, a flowmeter, a compensating bag and two non-return valves. Immediately before the solenoid valve a small quantity of exhaled air is preferably continuously withdrawn through a sampling line and then fed into the exhaled air via a CO2 analyser.

To measure the CO2 content of the inhaled air, 5 % of the stroke volume of the inhalation phase of the breathing machine is drawn off at the marked place by an auxiliary lung and fed to a CO2 analyser. The total dead space of the gas path (excluding the breathing machine) of the test installation should not exceed 2000 ml. Measure the carbon dioxide content of the inhaled air and record continuously. Test conditions are ambient atmospheric conditions. The ambient carbon dioxide level is measured 1 m in front of and level with the tips of the nose of the dummy head. The ambient level is measured once a stabilized level for carbon dioxide in the inhalation air has been attained. Alternatively, the ambient level of carbon dioxide may be measured at the sampling tube with the carbon dioxide supply turned off. Results are deemed acceptable only if the measured value of the ambient level of carbon dioxide is less than 0,1 %

Test results:
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
41	As received	0,91	0,89	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 EN 149:2001 + A1:2009 given in 7.12
42		0,83			
43		0,92			

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Test Standard: EN 149:2001+A1:2009 / EN 13274-3:2001
Name of tests: Breathing Resistance Testing-Inhalation/Exhalation Resistance
Reference no: BRT-001

Test Purpose:
This test method is used to measure that inhalation and exhalation resistance values.

Sampling method:
A total of nine particle filtering half masks have been tested: three in the state as received, three the simulated wearing treatment and three samples after the temperature conditioning.

Testing methods used:
A test method for determining inhalation and exhalation resistance testing in accordance with standard EN 13274-3:2001 / EN 149:2001 + A1:2009 clause 7.16

Test conditions:
The six test samples were conditioned in accordance with temperature conditioning and simulated wearing treatment.

Test Principle:
The device is placed on a support as specified in the relevant device standard and connected to the respirator adjusted to the respiratory volume at the specified minute.
While respiratory resistance is reported; If the pressure inside the facial part is negative compared to atmospheric pressure during the inhalation resistance test, no sign is put in front of the result, and when the relative pressure inside the face protector is positive, a "+" sign is placed in front of the result.

Test Equipment:
A sinus-shaped breathing apparatus. Device support as described in the relevant device standard, for example, Sheffield mannequin head with attachments or mannequin body with attachments.
Calibrated within the appropriate range and the accuracy of the breathing resistance limit specified in the relevant device standard pressure gauge which is better than 10% of its value.

Test Procedure:
The respirator is adjusted in accordance with its shape to deliver the respiratory volume in the minute specified in the relevant device standard.
One mouth of the pressure meter is connected to the pressure mouth of the support of the device and the other mouth to the environment. The pressure gauge is connected to the recorder device.
The device is leakproofly mounted on the support without any deformity. For headers that [illegible] the relevant fitting should be used. The "zero" reading of the pressure gauge is noted. The breathing machine switch is opened and the device is operated as described in the relevant device standard and the peak pressure is recorded.

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Test results:
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
29	As received	0,5	FFP1 ≤ 0,60 FFP2 ≤ 0,70 FFP3 ≤ 1,0	1,5	FFP1 ≤ 2,10 FFP2 ≤ 2,40 FFP3 ≤ 3,00	Passed
30		0,4		1,3		Passed
31		0,5		1,6		Passed
1	Simulated wearing treatment	0,5		1,4		Passed
2		0,6		1,5		Passed
3		0,5		1,4		Passed
13	Temperature conditioned	0,5		1,6		Passed
14		0,5		1,7		Passed
15		0,5		1,7		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
29	As received	160l/min	2,2	2,1	2,1	2,3	2,0	FFP1 ≤ 3,0 FFP2 ≤ 3,0 FFP3 ≤ 3,0	Passed
30			2,0	2,0	2,1	2,0	2,4		Passed
31			2,2	2,1	1,9	2,1	2,0		Passed
1	Simulated wearing treatment		2,2	2,2	2,0	2,3	2,4		Passed
2			2,0	2,3	2,0	2,0	2,2		Passed
3			2,1	2,3	2,0	2,1	2,1		Passed
13	Temperature conditioned		2,0	2,4	2,4	2,2	2,3		Passed
14			2,1	2,2	2,1	2,2	2,1		Passed
15			2,0	2,1	1,9	2,0	2,0		Passed

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CERTIFICATION

TECHNICAL ASSESSMENT REPORT

REPORT DATE / NO: 28.04.2020 / 2163-PPE-640

Client: Guangdong YIDAO Medical Technology Co., LTD.
Address: Room 302, Building 2, No. 3, Lane 1, Xijin Road, Hengli, Dongguan City, Guangdong Province, P.R. CHINA

This report is for the, given above, manufacturer prepared according to the test results obtained for the product dated 25.04.2020 with ID 04-2020-T-053 based on EN 149: 2001 + A1: 2009 standard. 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 No. 2163 - PPE - 639 issued to the manufacturer. The test results and issued certificate belongs only to the tested model. The technical report consists of a total of 7 pages.

Product Description : Particle Filtering Half Mask
Total Inward Leakage: Classification – FFP2
Trademark : YIDAO
Model : YD-002

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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 nuisance factors

PPE must be 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 addressof 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 deadlineor period of obsolescence of PPEor 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 inaccordance with Article5(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

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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 it is to be used.
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 given to these types or classes of must preferably take the form of harmonized pictograms or ideograms and must rem ain perfectly legible throughout the foreseeableuseful 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, in 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.

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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 — **Materials:** Materials used in particle filtering half masks, according to the simulated wearing treatment and temperature conditioning reports, It is understood without 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.

Article 3.6 — **Cleaning / Disinfection:** Particle Filtering half mask is not designed to be as re-usable.

Practical Performance :

Assessed Elements	Positive	Negative	Requirements in accordance with EN 149:2001 + A1:2009 and Result
1 The face piece fitting	2	0	Positive results should be obtained from the performance tests related to the implementation under real conditions. **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 compatibility with skin	2	0	

Article 7.7 — **Conditioning :** (A.R.) As Received, original

Article 7.8 — **Finish of Parts:** Particle filtering half masks, which are likely to come into contact with the user, do not have sharp edges and do not contain burrs.

Article 7.9.1 — **Total Inward Leakage:**

Test Subject	No of sample	Condition	1. Walk	Head left right	Head up down	Speech	2. Walk	Average
1	32	A.R	4.93	5.21	4.68	5.16	4.77	4.98
2	33	A.R	4.96	5.33	4.81	5.50	4.79	5.07
3	34	A.R	4.85	5.02	4.82	5.65	4.91	5.20
4	35	A.R	4.77	5.56	4.72	5.49	4.86	5.01
5	36	A.R	4.82	5.52	4.65	5.64	4.72	5.10
6	16	T.C	5.11	5.41	5.01	5.32	5.10	5.21
7	17	T.C	5.25	5.49	5.26	5.46	5.15	5.33
8	18	T.C	5.29	5.33	5.23	5.36	5.16	5.05
9	19	T.C	5.54	5.22	5.30	5.48	5.21	5.11
10	20	T.C	5.24	5.32	5.19	5.46	5.28	5.21
Average			5.06	5.36	4.97	5.43	4.97	5.16
Min			4.77	4.52	4.65	5.16	4.66	4.98
Max			5.34	5.62	5.30	5.51	5.26	5.33

Conditioning : (A.R.) As Received, original — Results P (%) Leakage Value
(T.C.) Temperature conditioning
Results meet with FFP2 requirements

Penetration of filter material: Sodium Chloride Testing

Condition	No. of Sample	Sodium Chloride Testing 95 L/min max (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	23	3,82	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	Filtering half masks fulfil 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.)	24	3,76		
(A.R.)	25	3,90		
(S.W.)	1	4,14		
(S.W.)	2	4,16		
(S.W.)	3	4,20		
(M.S. T.C.)	7	4,65		
(M.S. T.C.)	8	4,78		
(M.S. T.C.)	9	4,69		

Article 7.9.3

Conditioning : (M.S.) Mechanical Strength — 95 L/min = 1,6 dm³/m²
(T.C.) Temperature Conditioning
(A.R.) As Received, original
(S.W.) Simulated wearing treatment

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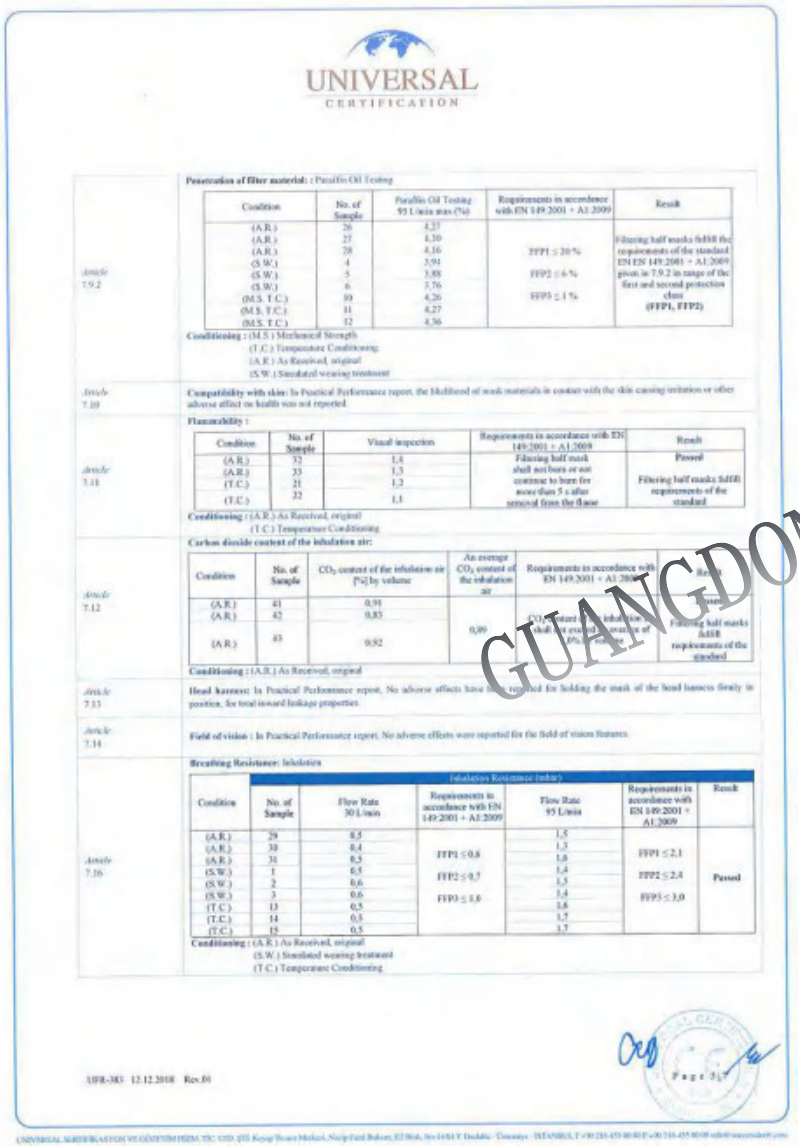

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Penetration of filter material: : Paraffin Oil Testing

Condition	No. of Sample	Paraffin Oil Testing 95 L/min max (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	26	4,27		
(A.R.)	27	4,30		
(A.R.)	28	4,16	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)
(S.W.)	4	2,91		
(S.W.)	5	3,88	FFP2 ≤ 6 %	
(S.W.)	6	3,76		
(M.S. T.C.)	10	4,26	FFP3 ≤ 1 %	
(M.S. T.C.)	11	4,27		
(M.S. T.C.)	12	4,36		

Article 7.9.2

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

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.)	32	1,4	Filtering half mask shall not burn or not continue to burn for more than 5 s after removal from the flame	Passed
(A.R.)	33	1,3		
(T.C.)	21	1,2		Filtering half masks fulfill requirements of the standard
(T.C.)	22	1,1		

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.)	41	0,91			
(A.R.)	42	0,83	0,89	(S.W.) Content of inhalation air shall not exceed an average of 1% by volume	Filtering half masks fulfill requirements of the standard
(A.R.)	43	0,92			

Conditioning : (A.R.) As Received, original

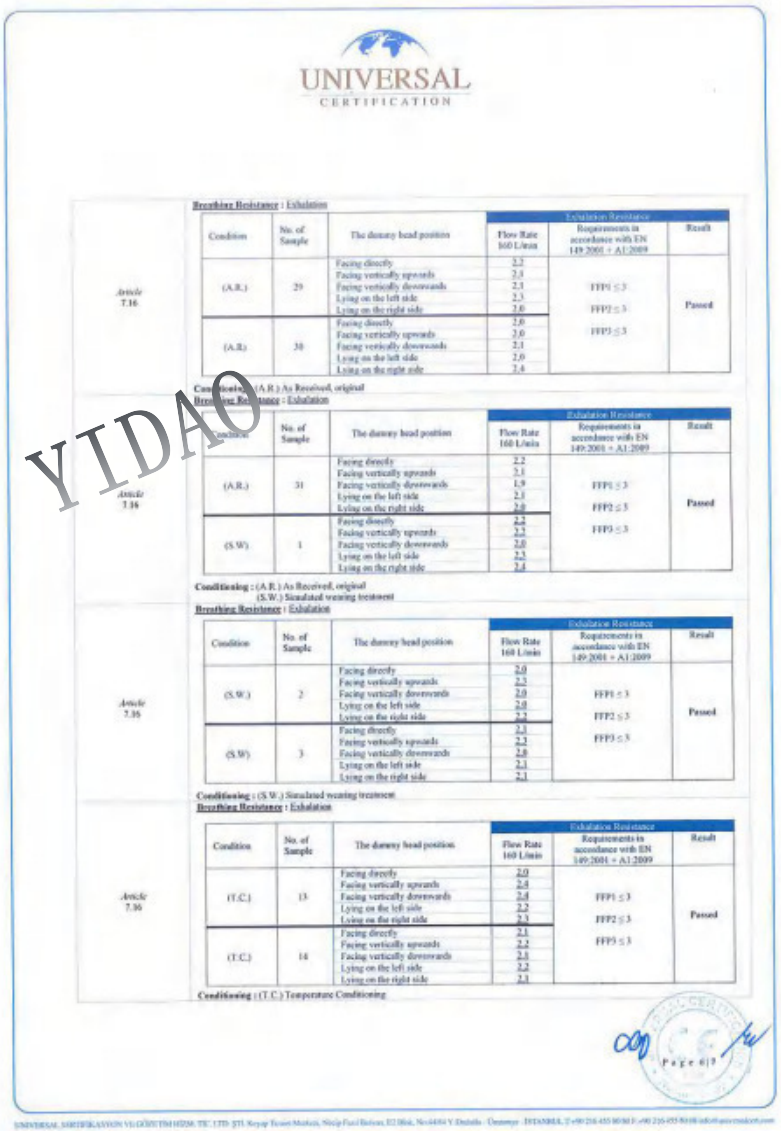
Article 7.13 — **Head harness:** In Practical Performance report, No adverse effects have been reported for holding the mask of the head harness firmly in position, for total inward leakage properties.

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

Condition	No. of Sample	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	Result
(A.R.)	29	0,5	FFP1 ≤ 0,6 FFP2 ≤ 0,7 FFP3 ≤ 1,0	1,5	FFP1 ≤ 2,1 FFP2 ≤ 2,4 FFP3 ≤ 3,0	Passed
(A.R.)	30	0,4		1,3		
(A.R.)	31	0,5		1,6		
(S.W.)	1	0,5		1,4		
(S.W.)	2	0,6		1,5		
(S.W.)	3	0,6		1,4		
(T.C.)	13	0,5		1,6		
(T.C.)	14	0,5		1,7		
(T.C.)	15	0,5		1,7		

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



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Article 7.16 — **Breathing Resistance :** Exhalation

Condition	No. of Sample	The dummy head position	Exhalation Resistance Flow Rate 160 L/min	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	29	Facing directly	2,3	FFP1 ≤ 3 FFP2 ≤ 3 FFP3 ≤ 3	Passed
		Facing vertically upwards	2,0		
		Facing vertically downwards	2,3		
		Lying on the left side	2,3		
		Lying on the right side	2,0		
(A.R.)	30	Facing directly	2,6		
		Facing vertically upwards	2,6		
		Facing vertically downwards	2,1		
		Lying on the left side	2,6		
		Lying on the right side	2,4		

Conditioning : (A.R.) As Received, original
Breathing Resistance : Exhalation

Condition	No. of Sample	The dummy head position	Exhalation Resistance Flow Rate 160 L/min	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	31	Facing directly	2,2	FFP1 ≤ 3 FFP2 ≤ 3 FFP3 ≤ 3	Passed
		Facing vertically upwards	2,1		
		Facing vertically downwards	1,9		
		Lying on the left side	2,1		
		Lying on the right side	2,0		
(S.W.)	1	Facing directly	2,2		
		Facing vertically upwards	2,2		
		Facing vertically downwards	2,0		
		Lying on the left side	2,2		
		Lying on the right side	2,4		

Conditioning : (A.R.) As Received, original
(S.W.) Simulated wearing treatment

Article 7.16 — **Breathing Resistance :** Exhalation

Condition	No. of Sample	The dummy head position	Exhalation Resistance Flow Rate 160 L/min	Requirements in accordance with EN 149:2001 + A1:2009	Result
(S.W.)	2	Facing directly	2,0	FFP1 ≤ 3 FFP2 ≤ 3 FFP3 ≤ 3	Passed
		Facing vertically upwards	2,3		
		Facing vertically downwards	2,0		
		Lying on the left side	2,0		
		Lying on the right side	2,2		
(S.W.)	3	Facing directly	2,1		
		Facing vertically upwards	2,2		
		Facing vertically downwards	2,0		
		Lying on the left side	2,1		
		Lying on the right side	2,1		

Conditioning : (S.W.) Simulated wearing treatment

Article 7.16 — **Breathing Resistance :** Exhalation

Condition	No. of Sample	The dummy head position	Exhalation Resistance Flow Rate 160 L/min	Requirements in accordance with EN 149:2001 + A1:2009	Result
(T.C.)	13	Facing directly	2,0	FFP1 ≤ 3 FFP2 ≤ 3 FFP3 ≤ 3	Passed
		Facing vertically upwards	2,4		
		Facing vertically downwards	2,0		
		Lying on the left side	2,2		
		Lying on the right side	2,3		
(T.C.)	14	Facing directly	2,1		
		Facing vertically upwards	2,2		
		Facing vertically downwards	2,1		
		Lying on the left side	2,2		
		Lying on the right side	2,1		

Conditioning : (T.C.) Temperature Conditioning

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Article 7.16	**Breathing Resistance :** Exhalation					
	Condition	No. of Sample	The dummy head position	Exhalation Resistance: Flow Rate 160 L/min	Requirements in accordance with EN 149:2001 + A1:2009	Result
	(T.C.)	15	Facing directly	2.0	FFP1 ≤ 3	Passed
			Facing vertically upwards	2.1		
			Facing vertically downwards	1.9	FFP2 ≤ 3	
			Lying on the left side	2.0		
			Lying on the right side	2.0	FFP3 ≤ 5	
	Conditioning : (T.C.) Temperature Conditioning					
Article 7.17.2	**Clogging :** This test is not applied to Particle Filtering Half Mask which is not reusable. *(For single shift use devices, the clogging test is optional test. For re-usable devices test is mandatory.)*					
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 8	**Marking – Packaging:** Necessary markings are available on the product and its packaging.					
Article 10	**Information to be supplied by the manufacturer:** In each of the smallest commercial packages of the product, information (installation instruction) pre-use controls, storing and usage limitations, storage and meanings of symbols / pictograms are defined.					

PREPARED BY	APPROVED BY
Mert TÜKENMEZ PPE Expert	**Sunt KAÇMAZ** General Manager

F D A 证书
FDA certificate

We are under the examine and approve for the USA EUA / WHITE LIST

Fiscal Year 2020

CERTIFICATION OF REGISTRATION

This certifies that:

Guangdong YIDAO Medical Technology Co., LTD.
Room 302, Building 2, No. 1, Lane 1, Xiju Road, Hengli, Dongguan City, Guangdong, 523000, China.
Was registered with US Food and Drug Administration, Center for devices and Radiological Health, pursuit to the Code of Federal Regulations 21 CFR 807.

Owner/Operator Number: 10068352

Listing Number	Premarket Submission Number/Type	Proprietary Name	Device Class	Product Codes	Activities
D388217	Exempt	Disposable protective mask, YD-001	ACCESSORY, SURGICAL APPAREL	[illegible]	Manufacturer
D388223	Exempt	KN95 protective mask, YD-002	RESPIRATOR, SURGICAL	MSH	Manufacturer

FDA Owner/OPERATOR NUMBER QUERY URL:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

We confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. The U.S. Food and Drug Administration makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole Be used for FDA Show off Owner/Operator Number. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration.

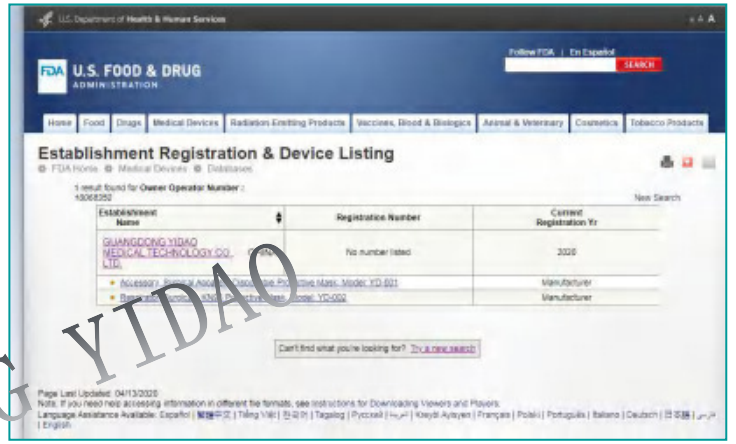
Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding". The U.S. Food and Drug Administration does not issue a certificate of registration, This certificate is used as FDA company information display only, nor does the U.S. Food and Drug Administration recognize or issue any kind a certificate of registration.

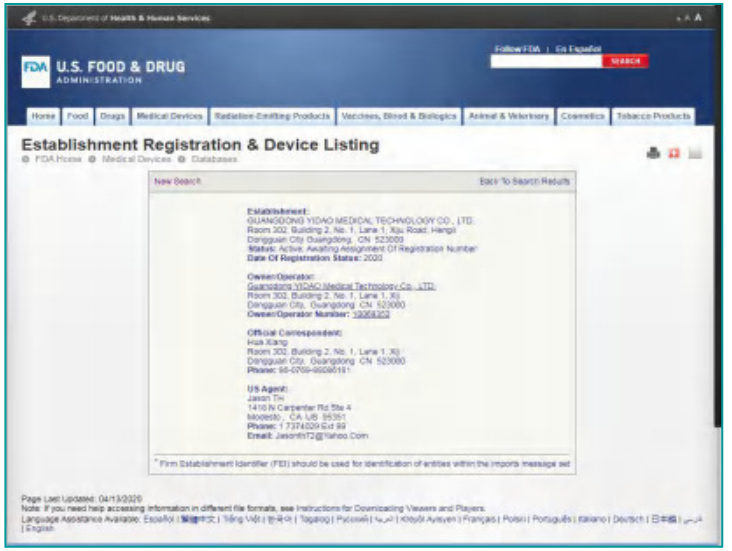
Issued: April 08, 2020

Expiration Date: Dec 31, 2020

Address: Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Contact Number: 1-888-INFO-FDA
(1-888-463-6332)
https://www.fda.gov





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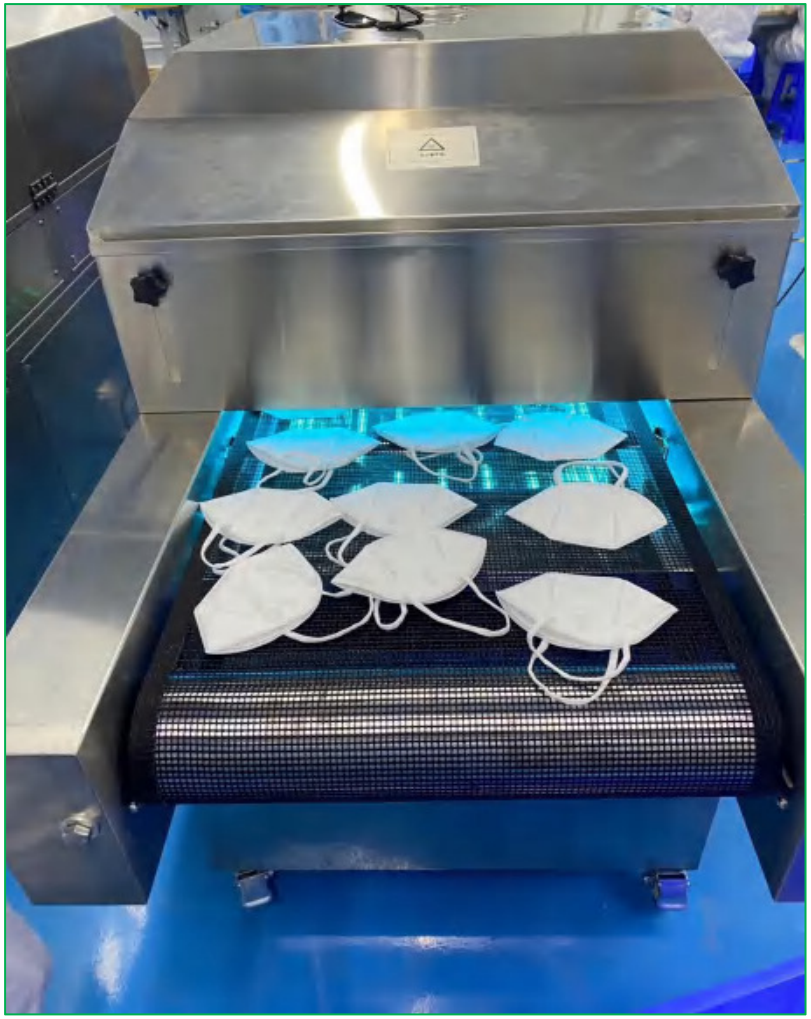
UV Disinfection and Sterilization



Factory's Testing Laboratory

产品细节
Products Details

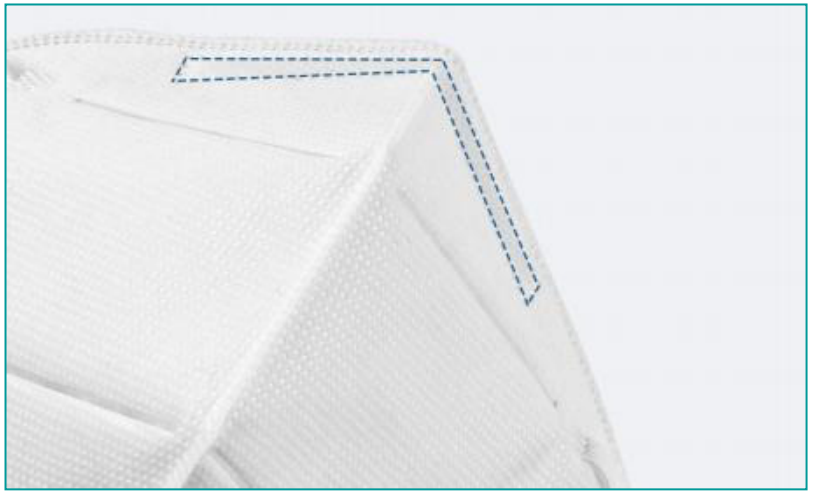
Inside stable nose bridge

Durable elastic lanyard
Fully automatic embossing

Five-layer design:
Inner and outer skin-friendly non-woven fabric, two layers of melt-blown cloth wrapped with filling layer

产品细节

Products Details



产品实物图

Product Photo

安装佩戴
Installation

1.With the nose clip facing outwards,pull the ear straps with each hand.
2.Cover your nose,mouth and chin with a protecitve mask.
3.Pull the ear strap behind your ear and adjust the ear strap to comfort.
4.Place your fingers in the middle of the nose clip and press inward as you move along the clip to the sides until the clip is fully attached to the bridge of nose.

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NB 2163

CERTIFICATE OF CONFORMANCE

Certificate Nr: 2163-PPE-639/01

Respiratory protective devices, filtering half masks to protect against particles manufactured by

Guangdong YIDAO Medical Technology Co., LTD.

at the following manufacturing site

Room 302, Building 2, No. 1, Lane 1, Xiju Road, Hengli, Dongguan City, Guangdong Province, P. R. CHINA

Continues to fulfil the requirements of

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

Based on the evaluation of test reports and internal quality control audit reports according to EN 149+A1:2009 and Personal Protective Equipment Regulation (EU) 2016/425 Annex VII (Module C2). This certificate implies that the manufactured products show below are in conformance with the approved EU Type Examination model and meets the requirements of the regulation. The details of compliance is given in technical report numbered **2163-PPE-640/01**

Product Definition

Model	Class	EU Type Examination Certificate		
		Serial Nr.	Date	Issuing NB Nr.
YD-002	FFP2	2163-PPE-639	28/04/2020	2163

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**.
- Taking all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type examination certificate.

This certificate is issued on **28/04/2020** and will be valid for one year, until **27/04/2021** if the manufacturer makes no major change in the product designs and manufacturing processes affecting the product performance on the essential health and safety requirement.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

The validity of this certificate can be verified online.

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NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate Nr: 2163-PPE-639

Respiratory protective devices, filtering half masks to protect against particles manufactured by

Guangdong YIDAO Medical Technology Co., LTD.

Room 302, Building 2, No. 1, Lane 1, Xiju Road, Hengli, Dongguan City, Guangdong Province, P. R. 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. The details of essential requirement compliance is given in technical report numbered **2163-PPE-640.**

Product Definition

Brand Name: YPHD **Model:** YD-002

Filtering half mask

Total Inwards Leakage: Class – FFP2

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 **28/04/2020** and will be valid for 5 years if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.

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Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

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TEST REPORT

EN 149:2001 + A1:2009

Particle Filtering Half Masks

Client:	Guangdong YIDAO Medical Technology Co., LTD.
Manufacturing Address:	Room 302, Building 2, No. 1, Lane 1, Xiju Road, Hengli, Dongguan City, Guangdong Province, P.R. CHINA
Model (s):	YD-002 FFP2 NR without valve
Sample received on:	April 07, 2020
Report Number:	NPT/20040712669
Elaborated by:	Ashley Madison
Place and date of issue:	Sheridan, WY April 25, 2020

Dr. Joseph Andrew, Ph.D.
Head of Testing Laboratory

Testing Laboratory: 1309 Coffeen Avenue STE 1200, Sheridan, WY, 82801, USA
Tel.:307-207-4535 Fax: 307-207-4535 E-mail: mdd@nptesting.com www.nptesting.com

TEST RESULT DETAILS (EN 149:2001 + A1:2009)

7.4 Packaging (EN 149:2001 + A1:2009 clause 8.2)	
The masks were not packaged as offered for sale. Manufacturer to certify regarding the final packaging to be used.	*NAs*
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.	*Passed*

7.5 Material (EN 149:2001 + A1:2009 clause 8.2, 8.3.1, 8.3.2)	
The materials used were able to withstand handling and wear during the limited laboratory testing carried out.	*Passed*
The effect on materials from "in-use" environmental factors could not be evaluated during laboratory tests. Manufacturer to certify regarding such factors.	*NAs*
Samples were conditioned in accordance with 8.3.1. None of the specimens conditioned suffered mechanical failure or collapse.	*Passed*
Samples were conditioned in accordance with 8.3.2. None of the specimens conditioned suffered collapse.	*Passed*

7.6 Cleaning and Disinfecting (EN 149:2001 + A1:2009 clause 8.4, 8.5, 8.11)	
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*

7.7 Practical Performance (EN 149:2001 + A1:2009 clause 8.4)	
See tested reference number PPT-001	*Passed*

7.8 Finish of Parts (EN 149:2001 + A1:2009 clause 8.2)	
None of the specimens used in laboratory testing showed evidence of sharp edges or burrs.	*Passed*

7.9.1 Total Inward Leakage (EN 149:2001 + A1:2009 clause 8.5)	
See tested reference number TIL-001	*Passed*

7.9.2.a Penetration of Filter Material-Sodium Chloride (EN 149:2001 + A1:2009 clause 8.11 & EN 13274-7:2019)	
See tested reference number SCT-001	*Passed*
7.9.2.b Penetration of Filter Material-Paraffin Oil (EN 149:2001 + A1:2009 clause 8.11 & EN 13274-7:2019)	
See tested reference number POT-001	*Passed*

7.10 Compatibility with skin (EN 149:2001 + A1:2009 clause 8.4, 8,5)	
No problems were encountered during practical performance testing.	*Passed*
No problems were encountered during total inward leakage testing.	*Passed*
The likelihood of materials in contact with the skin causing irritation or other adverse effect on health was not assessed. Manufacturer to certify.	*NAs*

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7.11 Flammability (EN 149:2001 + A1:2009 clause 8.6)	
See tested reference number FT-001	*Passed*

7.12 Carbon dioxide content of the inhalation air (EN 149:2001 + A1:2009 clause 8.7)	
See tested reference number CDT-001	*Passed*

7.13 Head harness (EN 149:2001 + A1:2009 clause 8.4, 8.5)	
The head harness was designed to allow the particle filtering half-mask to be donned and removed easily during limited practical performance and total inward leakage testing.	*Passed*
The head harness was adjustable and there were no adverse comments regarding security following limited practical performance and total inward leakage testing.	*Passed*
The product satisfied the total inward leakage requirements.	*Passed*

7.14 Field of vision (EN 149:2001 + A1:2009 clause 8.4)	
There were no adverse comments following practical performance tests.	*Passed*

7.15 Exhalation Valve (EN 149:2001 + A1:2009 clause 8.2, 8.3.4, 8.8, 8.9.1)	
Not applicable	*N/A*

7.16 Breathing Resistance (EN 149:2001 + A1:2009 clause 8.9)	
See tested reference number BRT-001	*Passed*

7.17 Clogging (EN 149:2001 + A1:2009 clause 8.9, 8.10)	
This is optional test and not desired by client.	*NAs*

7.18 Demountable Parts (EN 149:2001 + A1:2009 clause 8.2)	
No demountable parts	*N/A*

8.3 Conditioning	
See tested reference number CS-001	*Passed*

Passed	*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.*

Conclusion:

Model	***Recommendation Level***
YD-002	*FFP2 NR*

Testing Laboratory: 1309 Coffeen Avenue STE 1200, Sheridan, WY, 82801, USA
Tel.:307-207-4535 Fax: 307-207-4535 E-mail: mdd@nptesting.com www.nptesting.com

Test Standard: EN 149:2001+A1:2009 / EN 13274-5:2001
Name of tests: Conditioning of Samples
Reference no: CS-001

Simulated wearing treatment
Conditioning by simulated wearing treatment has been carried out by the following process. 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.

In order to prevent excess water spilling out of the dummy's mouth and contaminating the particle filtering half mask the head has been inclined so that the water runs away from the mouth and is collected in a trap. The breathing machine was brought into operation, the saturator switched on and the apparatus allowed to stabilize. The particle filtering half mask under test has then been mounted on the dummy head. During the test time at approximately 20 min intervals the particle filtering half mask has been completely removed from the dummy head and refitted such that during the test period it is fitted ten times to the dummy head.

Temperature conditioning
Unless otherwise specified, 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.

In order to ensure that there is no thermal shock during the conditioning of the specimens, the temperature gradient has been less than 2 °C/min between phases at different temperatures, or between the beginning and the end of a thermal cycle.

Expose the particle filtering half masks to the following thermal cycle:
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

Mechanical strength
The apparatus consists of a steel case (K) which is fixed on a vertically moving piston (S), capable of being lifted up 20 mm by a rotating cam (N) and dropping down onto a steel plate (P) under its own mass as the cam rotates. The mass of the steel case shall be more than 10 kg. The weight of the steel plate onto which the steel case falls should be (at least) 10 times the weight of the steel case. This may be achieved by bolting the base plate to a hard solid floor.

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

No	*Conditioning Area*	*Samples Number*
1	Simulated wearing treatment	1-2-3-4-5-6 (As Received)
2	Temperature conditioning	7-8-9-10-11-12 (Sample after test of Mechanical Strength)
		13-14-15-16-17-18-19-20-21-22 (As Received)
3	Mechanical strength	7-8-9-10-11-12 (As Received)

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Test Standard: EN 149:2001+A1:2009 / EN 13274-2:2001
Name of tests: Practical Performance Testing
Reference no: PPT-001

Test Purpose:
This test method is used to determine practical performance when its purpose is fitted by subjects during use in the simulated application, it subjectively evaluates certain features, characteristics and functions of the device that cannot be evaluated by experiments described in other standards.

Sampling method:
A total of two particle filtering half masks have been tested: two in the state as received.

Testing methods used:
A test method for determining practical performance in accordance with standard EN 13274-2:2001 + EN 149:2001 + A1:2009 clause 7.7/8.4

Test conditions:
The test has been carried out in a normally lit area with a temperature of 16 ° C to 32 ° C and a relative humidity of 30% to 80%. The actual temperature and humidity conditions and noise level have been recorded.

Test Principle:
A total of 2 particle filtering half masks have been tested: both as received. All tests have been carried out by two test subjects at ambient temperature and the test temperature and humidity have been recorded. Prior to the test there has been an examination to assure that the particle filtering half mask is in good working condition and that it can be used without hazard. For the test, persons have been selected who are familiar with using such or similar equipment.

Test Equipment:
A small basket (approximate volume = 8 l) with chippings or other suitable material from a hopper

Test Procedure:
General: During the tests the particle filtering half mask shall be subjectively assessed by the wearer and after the test, comments on the following shall be recorded: a) head harness comfort; b) security of fastenings; c) field of vision; d) any other comments reported by the wearer on request.

Walking test: The subjects wearing normal working clothes and wearing the particle filtering half mask shall walk at a regular rate of 6 km/h on a level course. The test shall be continuous, without removal of the particle filtering half mask, for a period of 10 min.

Work simulation test: The particle filtering half mask shall be tested under conditions which can be expected during normal use. During this test the following activities shall be carried out in simulation of the practical use of the particle filtering half mask. The test shall be completed within a total working time of 20 min. The sequence of activities is at the discretion of the test house. The individual activities shall be arranged so that sufficient time is left for the comments prescribed.
a) walking on the level with headroom of (1,3 ± 0,2) m for 5 min;
b) crawling on the level with headroom of (0,70 ± 0,05) m for 5 min;
c) filling a small basket (see Figure 1, approximate volume = 8 l) with chippings or other suitable material from a hopper which stands 1,5 m high and has an opening at the bottom to allow the contents to be shovelled out and a further opening at the top where the basket full of chippings is returned. The subject shall stoop or kneel as he wishes and fill the basket with chippings. He shall then lift the basket and empty the contents back into the hopper. This shall be done 20 times in 10 min.

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

Number of sample: 39 (A.R), 40 (A.R)

Assessed elements	*Positive Assessment*	*Negative Assessment*	*Requirements in accordance with EN 149:2001+A1:2009*	*Assessment of Test Result Conformity / Nonconformity*
1. The face piece fitting	2	0	Filtering half masks should not have imperfections related to wearer's acceptance	Filtering half masks fulfill requirements of the standard EN 149:2001 + A1:2009 given in 7.7
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 compatibility with skin	2	0		No imperfections

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Test Standard: EN 149:2001+A1:2009 / EN 13274-1:2001
Name of tests: Total Inward Leakage Testing
Reference no: TIL-001

Test Purpose:
This test method is used to determine the total inward leakage in respiratory protective devices.

Sampling method:
A total of ten particle filtering half masks have been tested: five in the state as received and five after temperature conditioning.

Testing methods used:
A test method for determining total inward leakage in accordance with standard EN 13274-1:2001 + EN 149:2001 + A1:2009 clause 7.9.1/8.5.

Test conditions:
The five test samples were conditioned in accordance with temperature conditioning.

Test Principle:
The total inward leakage has been tested using sodium chloride aerosol. Prior to the test there has been an examination to ensure that the particle filtering half mask is in good working condition and that it can be used without hazard.
For the test, persons has been selected who are familiar with using such or similar equipment. A panel of ten clean-shaven persons (without beards or sideburns) has been selected covering the spectrum of facial characteristics of typical users (excluding significant abnormalities). It is to be expected that exceptionally some persons cannot be satisfactorily fitted with a particle filtering half mask. Such exceptional subjects has not been used for testing particle filtering half masks.

Test Equipment:
The test atmosphere shall preferably enter the top of the enclosure through a flow distributor, and be directed downwards over the head of the test subject at a minimum flow rate of 0,12 m/s. The concentration of the test agent inside the effective working volume shall be checked to be homogeneous. The flow rate should be measured close to the subject's head. A level treadmill is required capable of working at 6 km/h.

Test Procedure:
Ask the test subjects to read the manufacturer's fitting information and if more than one size of particle filtering half mask is manufactured, ask the test subject to select the size deemed by him to be the most appropriate. If necessary the test supervisor shall show the test subjects how to fit the particle filtering half mask correctly in accordance with the fitting information. Inform the test subjects that if they wish to adjust the particle filtering half mask during the test they may do so. However if this is done, repeat the relevant section of the test, having allowed the system to resettle. The test subjects shall have no indication of the results as the test proceeds.

After fitting the particle filtering half mask, ask each test subject 'Does the mask fit?' If the answer is 'Yes', continue the test. If the answer is 'No', take the test subject off the panel, report the fact and replace with another test subject.

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Test results:
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	32	A.R.	4,93	5,21	4,88	5,10	4,77	4,98
2	33	A.R.	4,96	5,32	4,89	5,41	4,79	5,07
3	34	A.R.	4,85	5,62	4,95	5,68	4,91	5,20
4	35	A.R.	4,77	5,56	4,75	5,30	4,66	5,01
5	36	A.R.	4,82	5,52	4,77	5,66	4,72	5,10
6	16	T.C.	5,11	5,41	5,11	5,34	5,10	5,21
7	17	T.C.	5,25	5,49	5,25	5,49	5,15	5,33
8	18	T.C.	5,29	4,32	5,16	5,34	5,16	5,05
9	19	T.C.	5,34	5,22	5,35	5,42	5,21	5,31
10	20	T.C.	5,24	5,32	5,37	5,38	5,26	5,31
Maximum permitted			All individual exercise results were not greater than 11 %					Not greater than 8%

Requirements in accordance with EN 149:2001+A1:2009	*Assessment of Test Result Conformity / Nonconformity*
at least 46 out of the 50 individual results shall be not greater than 25 % for FFP1 11 % for FFP2 5 % for FFP3 and at least 8 out of the 10 individual wearer means shall be not greater than 22 % for FFP1 8 % for FFP2 2 % for FFP3	Passed Filtering half masks fulfil requirements of the standard EN 149:2001 + A1:2009 given in 7.9.1 in range of the first, the second and the third protection class (FFP1, FFP2, FFP3)

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Test Standard: EN 149:2001+A1:2009 / EN 13274-7:2019
Name of tests: Penetration of filter material Sodium Chloride Testing
Reference no: SCT-001

Test Purpose:
This test method is used to measure that the penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1 in 7.9.2.

Sampling method:
A total of nine particle filtering half masks have been tested: three in the state as received, three the simulated wearing treatment and three samples after the mechanical strength test and temperature conditioning.

Testing methods used:
A test method for determining penetration of filter material sodium chloride testing in accordance with standard EN 13274-7:2019 / EN 149:2001 + A1:2009 clause 7.9.2

Test conditions:
The six test samples were conditioned in accordance with mechanical strength test and temperature conditioning, simulated wearing treatment.

Test Principle:
The Sodium Chloride Aerosol Challenge test is able to determine filtration efficiency measurements up to 99.999% l.
The sample is placed into the filter holder. Cone or molded masks and respirators are mounted to a test fixture and sealed into a cylinder filter holder to ensure that the mask is properly sealed.
Samples are subjected to aerosolized NaCl. The concentration of NaCl is measured before and after impact with the sample. The amount of NaCl that passes through the sample is used to calculate the filtration efficiency of the sample.

Test Equipment:
The test equipment consists four modules sodium chloride aerosol generator flow control, filter test chamber, flame photometer aerosol detector. Sodium chloride aerosol is detected before and after the filtering device under test by flame photometry.

Test Procedure:
The device shall be mounted in a leak tight manner on a suitable adaptor and subjected to the test(s), ensuring that components of the device that could affect filter penetration values such as valves and harness attachment points are exposed to the challenge aerosol.
In order to carry out tests on the filtration efficiency of the filter material against particulates, a 1.0% NaCl solution based on demineralized water is used.
From the above solution using a Collison atomizer, an aerosol is generated with a particle diameter of 600 nm and an average concentration of 8 mg / m3
The aerosol is passed through the tested complete filtering half mask, sealed in the test chamber, with an air flow rate of 95 l / min. The test aerosol concentration is determined before and after the test sample using flame photometry. Comparison of determined concentrations allows to determine the filtration efficiency of the tested sample in the range from 0.00001% to 100%.

Test results:
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*
23	As received	3,82	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 the second protection class (FFP1, FFP2)
24		3,76		
25		3,90		
1	Simulated wearing treatment	4,14		
2		4,16		
3		4,20		
7	Mechanical strength + Temperature conditioned	4,45		
8		4,78		
9		4,69		

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Test Standard: EN 149:2001+A1:2009 / EN 13274-7:2019
Name of tests: Penetration of filter material Paraffin Oil Testing:
Reference no: POT-001

Test Purpose:
This test method is used to measure that the penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1 in 7.9.2.

Sampling method:
A total of nine particle filtering half masks have been tested: three in the state as received, three the simulated wearing treatment and three samples after the mechanical strength test and temperature conditioning.

Testing methods used:
A test method for determining penetration of filter material sodium chloride testing in accordance with standard EN 13274-7:2019 / EN 149:2001 + A1:2009 clause 7.9.2

Test conditions:
The six test samples were conditioned in accordance with mechanical strength test and temperature conditioning, simulated wearing treatment.

Test Principle:
An aerosol of paraffin oil droplets is generated by atomising paraffin oil. The concentration of this aerosol is measured before and after the filter under test by means of a light scattering aerosol photometer. Determinations have been possible in the range < 0.001% to 100% filter penetration.

Test Equipment:
The test equipment consists four modules paraffin oil mist aerosol generator flow control, filter test chamber, scattered light aerosol detector. The aerosol mass concentration and particle size distribution has been measured within the filter test chamber.

Test Procedure:
Tests on the efficiency of filtration against liquid particles are carried out using a paraffin oil mist generated using a CP 27 DAB paraffin oil atomizer heated to 1000C. The liquid aerosol thus generated has an average concentration of 20 mg / m3 and an average particle diameter of 400 nm. The aerosol thus generated is passed through the tested complete filtering half mask, sealed in the test chamber, with an air flow rate of 95 l / min.
The concentration of the test aerosol before and after the sample is determined by means of laser photometry. Comparison of determined concentrations allows to determine the filtration efficiency test sample for liquid aerosols in the concentration range from 0.0001% to 100%.

Test results:
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*
26	As received	4,27	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 the second protection class (FFP1, FFP2)
27		4,20		
28		4,16		
4	Simulated wearing treatment	3,94		
5		3,88		
6		3,76		
10	Mechanical strength + Temperature conditioned	4,26		
11		4,27		
12		4,36		

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Test Standard: EN 149:2001+A1:2009 / EN 13274-4:2001
Name of tests: Flammability Testing
Reference no: FT-001

Test Purpose:
This test method is used to measure that the materials used in the device are not dangerous for the person using the device and do not possess highly flammable nature.

Sampling method:
A total of four particle filtering half masks have been tested: two in the state as received and two after temperature conditioning.

Testing methods used:
A test method for determining Flammability in accordance with standard EN 13274-4:2001 + EN 149:2001 + A1:2009 clause 7.11/8.6.

Test conditions:
The two test samples were conditioned in accordance with temperature conditioning.

Test Principle:
The filtering face pieces subjected to the test, are passed one by one through a flame with a temperature of 800°C +/- 50°C and at a speed of 6 cm/s. The respirators must not go on burning for more than 5 s after removal from the flame.

Test Equipment:
The test rig consists mainly of a propane cylinder with flow control device, pressure gauge, flash back arrester, specimen support, rotation motor with speed controller, and burner. The burner has been either be in accordance with 6.2 or with ISO 6941. The purity of the propane has been a minimum of 95 %.

Test Procedure:
The face piece is put on a metallic dummy head which is motorized such that it describes a horizontal circle with a linear speed, measured at the tip of the nose, of (60 ± 5) mm/s. The head is arranged to pass over a propane burner the position of which can be adjusted. By means of a suitable gauge, the distance between the top of the burner, and the lowest part of the face piece (when positioned directly over the burner) shall be set to (20 ± 2) mm.

With the head turned away from the area adjacent to the burner, the propane gas is turned on, the pressure adjusted to between 0,2 bar and 0,3 bar and the gas ignited. By means of a needle valve and fine adjustments to the supply pressure, the flame height had been set to (40 ± 4) mm. This is measured with a suitable gauge.

The temperature of the flame measured at a height of (20 ± 2) mm above the burner tip by means of a 1,5 mm diameter mineral insulated thermocouple probe, shall be (800 ± 50) °C. Failure to meet the temperature requirement indicates that a fault such as a partially blocked burner exists. This had been rectified before testing. The head is set in motion and the effect of passing the face piece once through the flame has been noted.

The test has been repeated to enable an assessment to be made of all materials on the exterior of the device. Any one component has been passed through the flame once only

Test results:
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*
32	As received	1,4	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 EN 149:2001 + A1:2009 given in 7.1
33		1,3		
21	Temperature conditioned	1,2		
22		1,1		

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Test Standard: EN 149:2001+A1:2009 / EN 13274-6:2001
Name of tests: Carbon dioxide content of the inhalation air Testing
Reference no: CDT-001

Test Purpose:
This test method is used to determine carbon dioxide content of the inhalation air.

Sampling method:
A total of three particle filtering half masks have been tested: all three in the state as received.

Testing methods used:
A test method for determining carbon dioxide content of the inhalation air in accordance with standard EN 13274-6:2001 + EN 149:2001 + A1:2009 clause 7.12/8.7.

Test conditions:
The atmosphere where the temperature is from 16 ° C to 32 ° C and the relative humidity is 20% to 80%.

Test Principle:
The device is attached to the Sheffield mannequin head / body as described in the device standard; In the case of complete hardware testing, an air supply is operated under the manufacturer's lowest conditions, unless otherwise specified in the relevant standard. Air containing carbon dioxide at a certain concentration is supplied from the respirator to the mannequin head / body at a given flow rate. The inhaled air is analysed for its carbon dioxide content.
The measured carbon dioxide level provides information on the assessment of the "dead volume" of the facial protective part rather than a "real" measurement of the carbon dioxide level in the inhaled air.

Test Equipment:
The test rig consists Breathing apparatus, Auxiliary lung, Solenoid valve, Sheffield Mannequin head, Non-return valve, Sampling pipe for breathing air, Flow meter, Carbon dioxide absorber, Balancer, Carbon dioxide supply, Carbon dioxide analyzer

Test Procedure:
The apparatus subjects the particle filtering half mask to a respiration cycle by the breathing machine. For this test the particle filtering half mask has been fitted securely in a leak-tight manner but without deformation to a Sheffield dummy head. Air has been supplied to it from a breathing machine adjusted to 25 cycles/min and 2,0 l/stroke and the exhaled air has a carbon dioxide content of 5 % by volume. If the design of the test equipment causes a CO2 build-up a CO2 absorber has been used in the inhalation branch between solenoid valve and breathing machine. The CO2 is fed into the breathing machine via a control valve, a flowmeter, a compensating bag and two non-return valves. Immediately before the solenoid valve a small quantity of exhaled air is preferably continuously withdrawn through a sampling line and then fed into the exhaled air via a CO2 analyser.

To measure the CO2 content of the inhaled air, 5 % of the stroke volume of the inhalation phase of the breathing machine is drawn off at the marked place by an auxiliary lung and fed to a CO2 analyser. The total dead space of the gas path (excluding the breathing machine) of the test installation should not exceed 2000 ml. Measure the carbon dioxide content of the inhaled air and record continuously. Test conditions are ambient atmospheric conditions. The ambient carbon dioxide level is measured 1 m in front of and level with the tips of the nose of the dummy head. The ambient level is measured once a stabilized level for carbon dioxide in the inhalation air has been attained. Alternatively, the ambient level of carbon dioxide may be measured at the sampling tube with the carbon dioxide supply turned off. Results are deemed acceptable only if the measured value of the ambient level of carbon dioxide is less than 0,1 %

Test results:
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*
41	As received	0,91	0,89	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 EN 149:2001 + A1:2009 given in 7.12
42		0,83			
43		0,92			

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Test Standard: EN 149:2001+A1:2009 / EN 13274-3:2001
Name of tests: Breathing Resistance Testing-Inhalation/Exhalation Resistance
Reference no: BRT-001

Test Purpose:
This test method is used to measure that inhalation and exhalation resistance values.

Sampling method:
A total of nine particle filtering half masks have been tested: three in the state as received, three the simulated wearing treatment and three samples after the temperature conditioning.

Testing methods used:
A test method for determining inhalation and exhalation resistance testing in accordance with standard EN 13274-3:2001 / EN 149:2001 + A1:2009 clause 7.16

Test conditions:
The six test samples were conditioned in accordance with temperature conditioning and simulated wearing treatment.

Test Principle:
The device is placed on a support as specified in the relevant device standard and connected to the respirator adjusted to the respiratory volume at the specified minute.
While respiratory resistance is reported; If the pressure inside the facial part is negative compared to atmospheric pressure during the inhalation resistance test, no sign is put in front of the result, and when the relative pressure inside the face protector is positive, a "+" sign is placed in front of the result.

Test Equipment:
A sinus-shaped breathing apparatus. Device support as described in the relevant device standard, for example, Sheffield mannequin head with attachments or mannequin body with attachments.
Calibrated within the appropriate range and the accuracy of the breathing resistance limit specified in the relevant device standard pressure gauge which is better than 10% of its value.

Test Procedure:
The respirator is adjusted in accordance with its shape to deliver the respiratory volume in the minute specified in the relevant device standard.
One mouth of the pressure meter is connected to the pressure mouth of the support of the device and the other mouth to the environment. The pressure gauge is connected to the recorder device.
The device is leakproofly mounted on the support without any deformity. For headers that seal the neck circumference, the relevant fitting should be used. The "zero" reading of the pressure gauge is noted. The breathing machine switch is opened and the device is operated as described in the relevant device standard and the peak pressure is recorded.

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Test results:
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
29	As received	0,5	FFP1 ≤ 0,60 FFP2 ≤ 0,70 FFP3 ≤ 1,0	1,5	FFP1 ≤ 2,10 FFP2 ≤ 2,40 FFP3 ≤ 3,00	Passed
30		0,4		1,3		Passed
31		0,5		1,6		Passed
1	Simulated wearing treatment	0,5		1,4		Passed
2		0,6		1,5		Passed
3		0,6		1,4		Passed
13	Temperature conditioned	0,5		1,6		Passed
14		0,5		1,7		Passed
15		0,5		1,7		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
29	As received	160l/min	2,2	2,1	2,1	2,3	2,0	FFP1 ≤ 3,0 FFP2 ≤ 3,0 FFP3 ≤ 3,0	Passed
30			2,0	2,0	2,1	2,0	2,4		Passed
31			2,2	2,1	1,9	2,1	2,0		Passed
1	Simulated wearing treatment		2,2	2,2	2,0	2,3	2,4		Passed
2			2,0	2,3	2,0	2,0	2,2		Passed
3			2,1	2,3	2,0	2,1	2,1		Passed
13	Temperature conditioned		2,0	2,4	2,4	2,2	2,3		Passed
14			2,1	2,2	2,1	2,2	2,1		Passed
15			2,0	2,1	1,9	2,0	2,0		Passed

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TECHNICAL ASSESSMENT REPORT

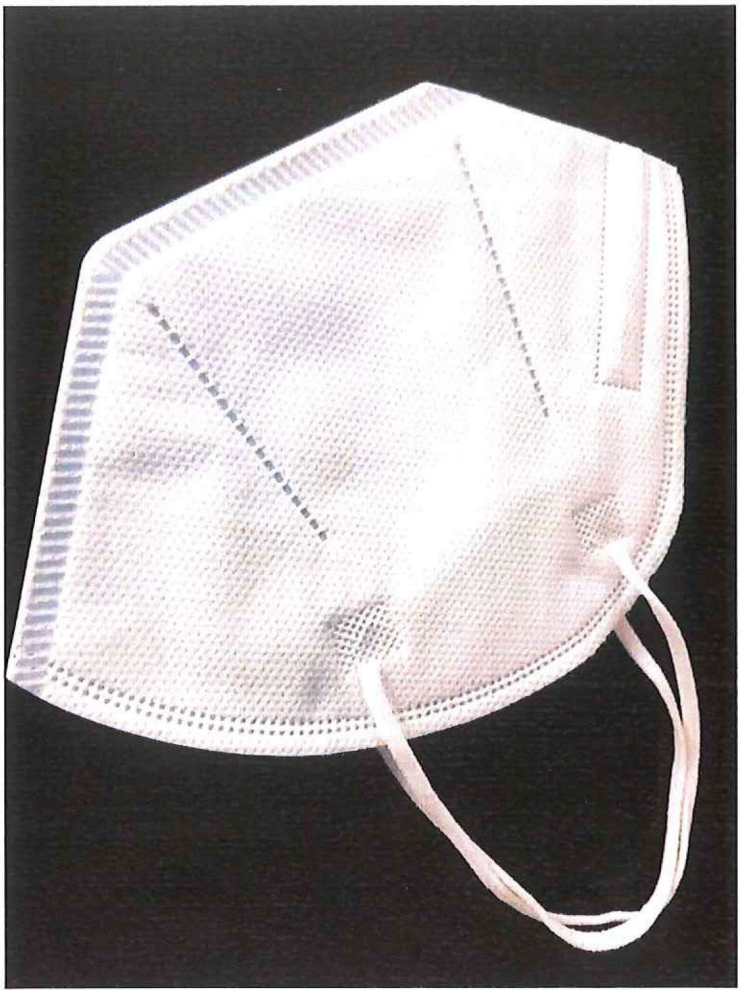
REPORT DATE / NO: 28.04.2020 / 2163-PPE-640

Client: Guangdong YIDAO Medical Technology Co., LTD.
Address: Room 302, Building 2, No. 1, Lane 1, Xiju Road, Hengli, Dongguan City, Guangdong Province, P.R. CHINA

This report is for the, given above, manufacturer prepared according to the test results obtained for the product dated 25.04.2020 with ID 04-2020-T-053 based on EN 149: 2001 + A1: 2009 standard, 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 Personel Protective Equipment Regulation and found to be appropriate.

This report is an annex and an integral part of the EU Type Examination Certificate No. 2163 - PPE - 639 issued to the manufacturer. The test results and issued certificate belongs only to the tested model. The technical report consists of a total of 7 pages.

Product Description : Particle Filtering Half Mask
Total Inward Leakage: Classification – FFP2
Trademark :YPHD
Model : YD-002



UNIVERSAL CERTIFICATION 2163 Notified Body

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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 prossible 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 fore seeable 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 permessible user impediment

Any inpediment 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 addressof 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 guestion;
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 deadlineor period of obsolescence of PPEor 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 inaccordance with Article5(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

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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 rem ain perfectly legible throughout the foreseeableuseful 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 al lor 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.

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UNIVERSAL
CERTIFICATION

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.

Article 7.6

Cleaning and Disinfection: Particle filtering half mask is not designed to be as re-usable.

Article 7.7

Practical Performance :

Assessed Elements	Positive	Negative	Requirements in accordance with EN 149:2001 + A1:2009 and Result
1.The face piece fitting	2	0	Positive results should be obtained from the performance tests related to the implementation under real conditions. **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 compatibility with skin	2	0	

Conditioning : (A.R.) As Received, original

Article 7.8

Finish of Parts: Particle filtering half masks, which are likely to come into contact with the user, do not have sharp edges and do not contain burrs.

Article 7.9.1

Total Inward Leakage:

Test Subject	No.of sample	Condition	1.Walk	Head left /right	Head up /down	Speech	2. Walk	Average
1	32	A.R	4,93	5,21	4,68	5,16	4,77	4,98
2	33	A.R	4,96	5,32	4,81	5,50	4,79	5,07
3	34	A.R	4,85	5,62	4,82	5,65	4,91	5,20
4	35	A.R	4,77	5,56	4,72	5,49	4,66	5,01
5	36	A.R	4,82	5,52	4,65	5,64	4,72	5,10
6	16	T.C.	5,11	5,41	5,02	5,32	5,10	5,21
7	17	T.C.	5,25	5,49	5,26	5,46	5,15	5,33
8	18	T.C.	5,29	4,32	5,23	5,36	5,16	5,05
9	19	T.C.	5,34	5,22	5,30	5,49	5,21	5,31
10	20	T.C.	5,24	5,32	5,19	5,46	5,26	5,31
Average			5,06	5,30	4,97	5,45	4,97	5,16
Min			4,77	4,32	4,65	5,16	4,66	4,98
Max			5,34	5,62	5,30	5,51	5,26	5,33

Conditioning : (A.R.) As Received, original
(T.C.) Temperature conditioning

Results P (%) Leakage Value

Results meet with FFP2 requirements

Article 7.9.2

Penetration of filter material: Sodium Chloride Testing

Condition	No. of Sample	Sodium Chloride Testing 95 L/min max (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	23	3,82	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	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.)	24	3,76		
(A.R.)	25	3,90		
(S.W.)	1	4,14		
(S.W.)	2	4,16		
(S.W.)	3	4,20		
(M.S. T.C.)	7	4,45		
(M.S. T.C.)	8	4,78		
(M.S. T.C.)	9	4,69		

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

95 L/min = 1,6 $dm^3.sn^{-1}$

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Article 7.9.2

Penetration of filter material: : Paraffin Oil Testing

Condition	No. of Sample	Paraffin Oil Testing 95 L/min max (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	26	4,27	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	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.)	27	4,20		
(A.R.)	28	4,16		
(S.W.)	4	3,94		
(S.W.)	5	3,88		
(S.W.)	6	3,76		
(M.S. T.C.)	10	4,26		
(M.S. T.C.)	11	4,27		
(M.S. T.C.)	12	4,36		

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

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.)	32	1,4	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.)	33	1,3		
(T.C.)	21	1,2		
(T.C.)	22	1,1		

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.)	41	0,91	0,89	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.)	42	0,83			
(A.R.)	43	0,92			

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.

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

Condition	Inhalation Resistance (mbar)					
	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.)	29	0,5	FFP1 ≤ 0,6 FFP2 ≤ 0,7 FFP3 ≤ 1,0	1,5	FFP1 ≤ 2,1 FFP2 ≤ 2,4 FFP3 ≤ 3,0	**Passed**
(A.R.)	30	0,4		1,3		
(A.R.)	31	0,5		1,6		
(S.W.)	1	0,5		1,4		
(S.W.)	2	0,6		1,5		
(S.W.)	3	0,6		1,4		
(T.C.)	13	0,5		1,6		
(T.C.)	14	0,5		1,7		
(T.C.)	15	0,5		1,7		

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

Article 7.16

Breathing Resistance : Exhalation

Condition	No. of Sample	The dummy head position	Exhalation Resistance		
			Flow Rate 160 L/min	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	29	Facing directly	2,2	FFP1 ≤ 3 FFP2 ≤ 3 FFP3 ≤ 3	Passed
		Facing vertically upwards	2,1		
		Facing vertically downwards	2,1		
		Lying on the left side	2,3		
		Lying on the right side	2,0		
(A.R)	30	Facing directly	2,0		
		Facing vertically upwards	2,0		
		Facing vertically downwards	2,1		
		Lying on the left side	2,0		
		Lying on the right side	2,4		

Conditioning : (A.R.) As Received, original

Article 7.16

Breathing Resistance : Exhalation

Condition	No. of Sample	The dummy head position	Exhalation Resistance		
			Flow Rate 160 L/min	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	31	Facing directly	2,2	FFP1 ≤ 3 FFP2 ≤ 3 FFP3 ≤ 3	Passed
		Facing vertically upwards	2,1		
		Facing vertically downwards	1,9		
		Lying on the left side	2,1		
		Lying on the right side	2,0		
(S.W)	1	Facing directly	2,2		
		Facing vertically upwards	2,2		
		Facing vertically downwards	2,0		
		Lying on the left side	2,3		
		Lying on the right side	2,4		

Conditioning : (A.R.) As Received, original
(S.W.) Simulated wearing treatment

Article 7.16

Breathing Resistance : Exhalation

Condition	No. of Sample	The dummy head position	Exhalation Resistance		
			Flow Rate 160 L/min	Requirements in accordance with EN 149:2001 + A1:2009	Result
(S.W.)	2	Facing directly	2,0	FFP1 ≤ 3 FFP2 ≤ 3 FFP3 ≤ 3	Passed
		Facing vertically upwards	2,3		
		Facing vertically downwards	2,0		
		Lying on the left side	2,0		
		Lying on the right side	2,2		
(S.W)	3	Facing directly	2,1		
		Facing vertically upwards	2,3		
		Facing vertically downwards	2,0		
		Lying on the left side	2,1		
		Lying on the right side	2,1		

Conditioning : (S.W.) Simulated wearing treatment

Article 7.16

Breathing Resistance : Exhalation

Condition	No. of Sample	The dummy head position	Exhalation Resistance		
			Flow Rate 160 L/min	Requirements in accordance with EN 149:2001 + A1:2009	Result
(T.C.)	13	Facing directly	2,0	FFP1 ≤ 3 FFP2 ≤ 3 FFP3 ≤ 3	Passed
		Facing vertically upwards	2,4		
		Facing vertically downwards	2,4		
		Lying on the left side	2,2		
		Lying on the right side	2,3		
(T.C.)	14	Facing directly	2,1		
		Facing vertically upwards	2,2		
		Facing vertically downwards	2,1		
		Lying on the left side	2,2		
		Lying on the right side	2,1		

Conditioning : (T.C.) Temperature Conditioning

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Article 7.16	**Breathing Resistance :** Exhalation

Condition	No. of Sample	The dummy head position	Exhalation Resistance		
			Flow Rate 160 L/min	Requirements in accordance with EN 149:2001 + A1:2009	Result
(T.C.)	15	Facing directly	2.0	FFP1 ≤ 3	Passed
		Facing vertically upwards	2.1		
		Facing vertically downwards	1.9	FFP2 ≤ 3	
		Lying on the left side	2.0		
		Lying on the right side	2.0	FFP3 ≤ 3	

Conditioning : (T.C.) Temperature Conditioning

Article 7.17.2	**Clogging :** This test is not applied to Particle Filtering Half Mask which is not reusable. *(For single shift use devices, the clogging test is optional test. For re-usable devices test is mandatory.)*
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:** Necessary markings are available on the product and its packaging.
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.

PREPARED BY	APPROVED BY
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