DOCUMENTATION

MASK ULTRA PROTECTION FFP2

MASCARILLA ULTRA PROTECCIÓN FFP2
MASQUE FFP2 ULTRA PROTECTION FFP2
MASCHERINA PROTEZIONE ULTRA FFP2

REF. CV-41
YD-002



MASTER BOX: 1000 pcs

CV-41

ITEM: YD-002
DESCRIPTION: NAAMIO
MATERIAL:
5 PLY (44% non woven, 30% Meltblown, 26% algodón).
QUANTITY: 1.000
G.W
N.W
CNT SIZE
BATCH NUMBER:
PRODUCTION DATE:
VALIDITY:

产品名称：FFP2防护口罩(非医用
执行标准：EN149:2001+A1:2009
生产厂商： 广东医道医疗科技有限公司
生产地址：广东省东莞市横沥镇西聚一巷1号2号楼302室

MADE IN P.R.C.

BOX: 25 pcs



BAG: 1 pc



EU DECLARE OF THE CONFORMITY

CE

We

Company Name:	Guangdong YiDao Medical Technology Co., Ltd
Postal address:	Room 302, Buildig 2, No. 1, Lane 1, Xiju Road, Hengli, Dongguan, Dongguan City,Guangdong, China
Postcode:	523000
City:	Dongguan
Telephone number	
Email:	

Declare that the DoC is issued under our sole responsibility and belongs to the following products:

Apparatus model/Product:	Disposable protective mask
type:	YD- 002

Object of the declaration(identification of apparatus allowing traceability. it may include a colour image of sufficient clarity where necessary for the identification of the appearance)



The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:

Personal protective equipment Regulation(EU)2016/425

The following harmonised standards and technical specifications have been applied:

Title,Date of standards/specification:

EN149:2001+A1:2009

Notified body(where applicable)	4 digit notified body number
UNIVERSAL CERTIFICATION AND SURVEILLLANCE TADE LTD,CO	2163
Certificate Number:	2163- PPE- 639
Technical report numbered:	2163- PPE- 640

Signed for and on behalf of

Guangdong,China — Place of issue

Jul.15.2020 — Date of issue

Name,function,signature
General Manager

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	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.

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Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

The validity of this certificate can be verified online.

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CERTIFICATION

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.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

The validity of this certificate can be verified online.

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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Note: The results given in this Test Report apply only to the sample tested by our laboratory!
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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*

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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 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% 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 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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Test Report

No. CANEC2006728501 Date: 20 May 2020 Page 1 of 10

GUANGDONG YIDAO MEDICAL TECHNOLOGY CO. LTD.

ROOM 302, BUILDING 2, NO. 1, LANE 1, XIJU ROAD, HENGLI, DONGGUAN, DONGGUAN CITY, GUANGDONG, CHINA.

The following sample(s) was/were submitted and identified on behalf of the clients as : KN95 Protective mask（Filtering half mask）

SGS Job No. :	CP20-021161 - SZ
Model No. :	YD-002
Date of Sample Received :	09 May 2020
Testing Period :	09 May 2020 - 14 May 2020
Test Requested :	Selected test(s) as requested by client.
Test Method :	Please refer to next page(s).
Test Results :	Please refer to next page(s).

Result Summary :

Test Requested	Conclusion
Entry 23 of Regulation (EU) 2016/217 amending Annex XVII of REACH Regulation (EC) No 1907/2006- Cadmium and its compounds	PASS
Entry 63 of Regulation (EU) No 2015/628 amending Annex XVII of REACH Regulation (EC) No 1907/2006 - Lead and its compounds	PASS
Entry 50 of Regulation(EU) 2015/326 amending Annex XVII of REACH Regulation (EC) No 1907/2006- Polycyclic Aromatic Hydrocarbons (PAHs)	PASS
Phthalate	See Results
Entry 20 of Regulation (EU) No 276/2010 amending Annex XVII of REACH Regulation (EC) No 1907/2006 –Organotin compounds	PASS

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

Violet Shi

Violet,Shi
Approved Signatory

SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch Testing Center Chemical Laboratory

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Test Results :

Test Part Description :

Specimen No.	SGS Sample ID	Description
SN1	CAN20-067285.001	White material 1A+White plastic 1B
SN2	CAN20-067285.002	White material 2A+White plastic 2B+White fabric 2C
SN3	CAN20-067285.003	White fabric 3A+White cotton 3B +White fabric 3C
SN4	CAN20-067285.004	White plastic 4#

Remarks :

(1) 1 mg/kg = 0.0001%
(2) MDL = Method Detection Limit
(3) ND = Not Detected (< MDL)
(4) "-" = Not Regulated

Entry 23 of Regulation (EU) 2016/217 amending Annex XVII of REACH Regulation (EC) No 1907/2006- Cadmium and its compounds

Test Method : With reference to EN 1122: 2001 method B. Analysis was performed by AAS.

Test Item(s)	CAS NO.	Limit	Unit	MDL	*004*
Cadmium (Cd)	7440-43-9	0.01	%(w/w)	0.0005	ND
Comment					**PASS**

Entry 63 of Regulation (EU) No 2015/628 amending Annex XVII of REACH Regulation (EC) No 1907/2006 - Lead and its compounds

Test Method : With reference to CPSC-CH-E1002-08.3, analysis was performed by ICP-OES.

Test Item(s)	Limit	Unit	MDL	*004*
Lead (Pb)	500	mg/kg	20	ND
Comment				**PASS**

Notes :

When the result is equal to or greater than 500 mg/kg, the limit shall not apply where it can be demonstrated that the rate of Lead release from such an article or any such accessible part of an article, whether coated or uncoated, does not exceed 0.05 µg/cm2/h (equivalent to 0.05 µg/g/h), it suggest to

检验检测专用章 Inspection & Testing Services

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use lead release test method EN 16711-3: 2019 for confirmation test.

Entry 50 of Regulation(EU) 2015/326 amending Annex XVII of REACH Regulation (EC) No 1907/2006- Polycyclic Aromatic Hydrocarbons (PAHs)

Test Method : With reference to AfPS GS 2019:01 PAK, analysis was performed by GC-MS.

Test Item(s)	CAS NO.	Limit	Unit	MDL	001
Benzo(a)anthracene(BaA)	56-55-3	1.0	mg/kg	0.1	ND
Chrysene(CHR)	218-01-9	1.0	mg/kg	0.1	ND
Benzo(b)fluoranthene(BbF)	205-99-2	1.0	mg/kg	0.1	ND
Benzo(j)fluoranthene (BjF)	205-82-3	1.0	mg/kg	0.1	ND
Benzo(k)fluoranthene(BkF)	207-08-9	1.0	mg/kg	0.1	ND
Benzo(a)pyrene(BaP)	50-32-8	1.0	mg/kg	0.1	ND
Benzo(e)pyrene(BeP)	192-97-2	1.0	mg/kg	0.1	ND
Dibenzo(a,h)anthracene(DBA)	53-70-3	1.0	mg/kg	0.1	ND
Comment					**PASS**

Notes :

The limit is specified by Entry 50 of Regulation(EU) 2015/326 amending Annex XVII of REACH Regulation (EC) No 1907/2006.
General Product Toys or Childcare Article
EU 8 PAHs 1.0mg/kg (each) 0.5mg/kg (each)
Composite test has been performed in equal proportion for the components/material per client requested. And the result is calculated using the total weight of mixed samples.

Phthalate

Test Method : With reference to EN 14372:2004 , analysis was performed by GC/MS.

Test Item(s)	CAS NO.	Unit	MDL	001
Dibutyl Phthalate (DBP)	84-74-2	%(w/w)	0.003	ND
Benzylbutyl Phthalate (BBP)	85-68-7	%(w/w)	0.003	ND
Bis(2-ethylhexyl) Phthalate (DEHP)	117-81-7	%(w/w)	0.003	ND
Diisobutyl Phthalate (DIBP)	84-69-5	%(w/w)	0.003	ND
Total (DBP + BBP + DEHP+DIBP)	-	%(w/w)	-	ND

Notes :

(1) DBP,BBP,DEHP, DIBP Reference information: Entry 51 of Regulation (EU) 2018/2005 amending Annex XVII of REACH Regulation (EC) No 1907/2006:
i) Shall not be used as substances or in mixtures, individually or in any combination of DBP, BBP, DEHP & DIBP, in concentrations equal to or greater than 0.1 % by weight of the plasticised material, in toys and

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childcare articles.
ii) Shall not be placed on the market in toys or childcare articles, individually or in any combination of DBP, BBP, DEHP, in concentrations equal to or greater than 0.1 % by weight of the plasticised material.
In addition, DIBP shall not be placed on the market after 7 July 2020 in toys or childcare articles, individually or in any combination of DBP, BBP, DEHP & DIBP, in concentrations equal to or greater than 0.1 % by weight of the plasticised material.
iii) shall not be placed on the market after 7 July 2020 in articles, individually or in any combination of DBP, BBP, DEHP & DIBP, in concentrations equal to or greater than 0.1 % by weight of the plasticised material in the articles.
Please refer to Regulation (EU) 2018/2005 to get more detail information
(2) Composite test has been performed in equal proportion for the components/material per client requested. And the result is calculated using the total weight of mixed samples.

Entry 20 of Regulation (EU) No 276/2010 amending Annex XVII of REACH Regulation (EC) No 1907/2006 – Organotin compounds

Test Method : SGS In-house method (GZTC CHEM-TOP-031, with reference to ISO 17353:2004), analysis was performed by GC-MS.

Test Item(s)	Limit	Unit	MDL	002
Tributyl tin (TBT) by weight of Tin	-	%(w/w)	0.01	ND
Triphenyl tin (TPhT) by weight of Tin	-	%(w/w)	0.01	ND
Tripropyltin (TPT) by weight of Tin	-	%(w/w)	0.01	ND
Tricyclohexyltin (TCyT) by weight of Tin	-	%(w/w)	0.01	ND
Trioctyltin (TOT) by weight of Tin	-	%(w/w)	0.01	ND
Trimethyltin(TMT) by weight of Tin	-	%(w/w)	0.01	ND
Σ of Tri substituted organotin compounds calculated as tin	0.1	%(w/w)	-	ND
Dibutyl tin (DBT) by weight of Tin	0.1	%(w/w)	0.01	ND
Dioctyl tin (DOT) by weight of Tin	0.1	%(w/w)	0.01	ND
Comment				**PASS**

Test Item(s)	Limit	Unit	MDL	003
Tributyl tin (TBT) by weight of Tin	-	%(w/w)	0.01	ND
Triphenyl tin (TPhT) by weight of Tin	-	%(w/w)	0.01	ND
Tripropyltin (TPT) by weight of Tin	-	%(w/w)	0.01	ND
Tricyclohexyltin (TCyT) by weight of Tin	-	%(w/w)	0.01	ND
Trioctyltin (TOT) by weight of Tin	-	%(w/w)	0.01	ND
Trimethyltin(TMT) by weight of Tin	-	%(w/w)	0.01	ND
Σ of Tri substituted organotin compounds calculated as tin	0.1	%(w/w)	-	ND
Dibutyl tin (DBT) by weight of Tin	0.1	%(w/w)	0.01	ND
Dioctyl tin (DOT) by weight of Tin	0.1	%(w/w)	0.01	ND
Comment				**PASS**

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Notes :

Composite test has been performed in equal proportion for the components/material per client requested. And the result is calculated using the total weight of mixed samples.

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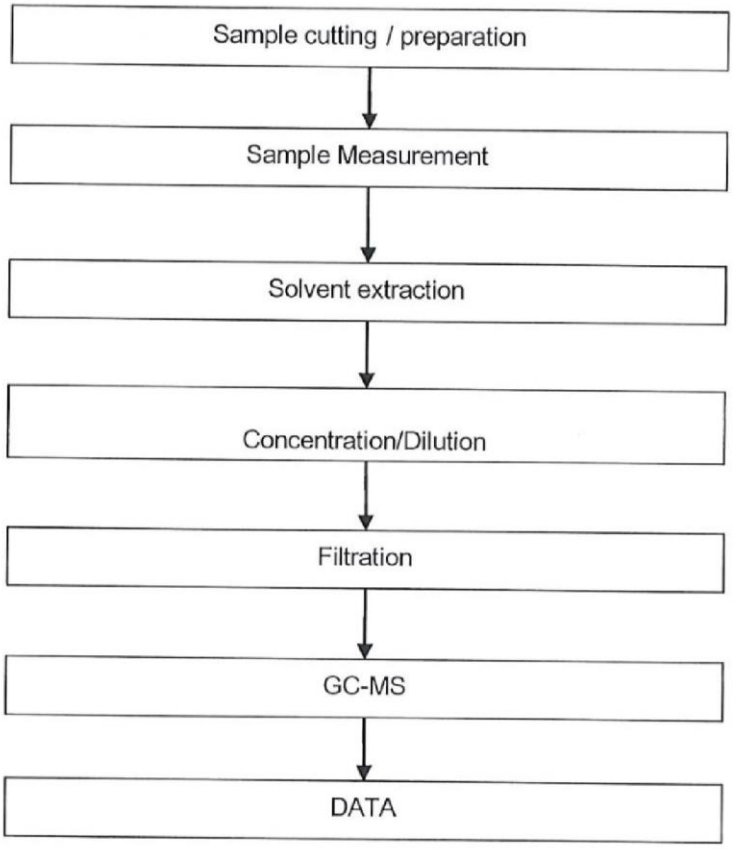
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Phthalates Testing Flow Chart

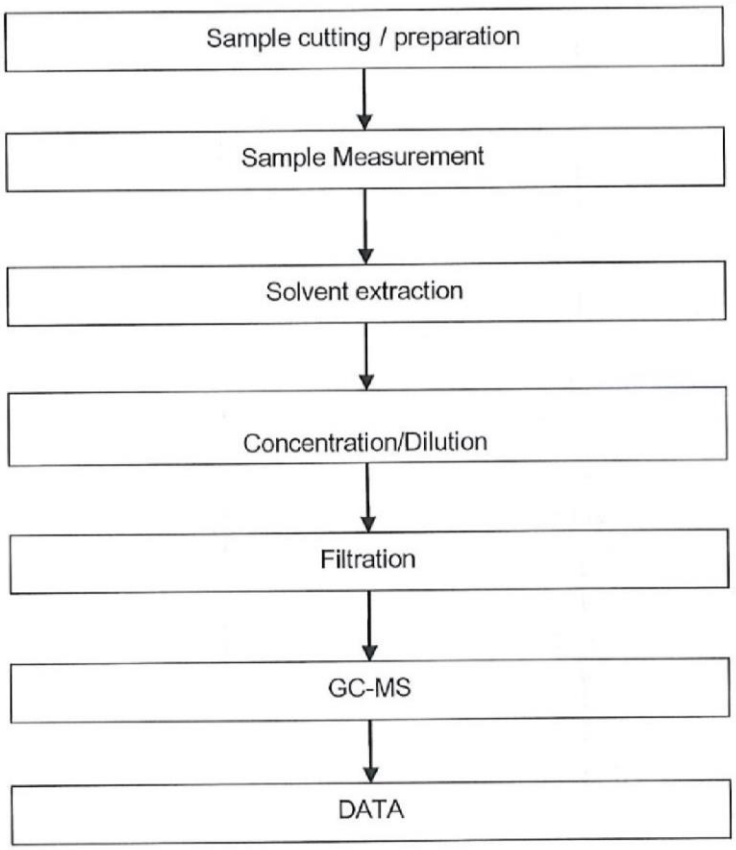


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PAHs Testing Flow Chart

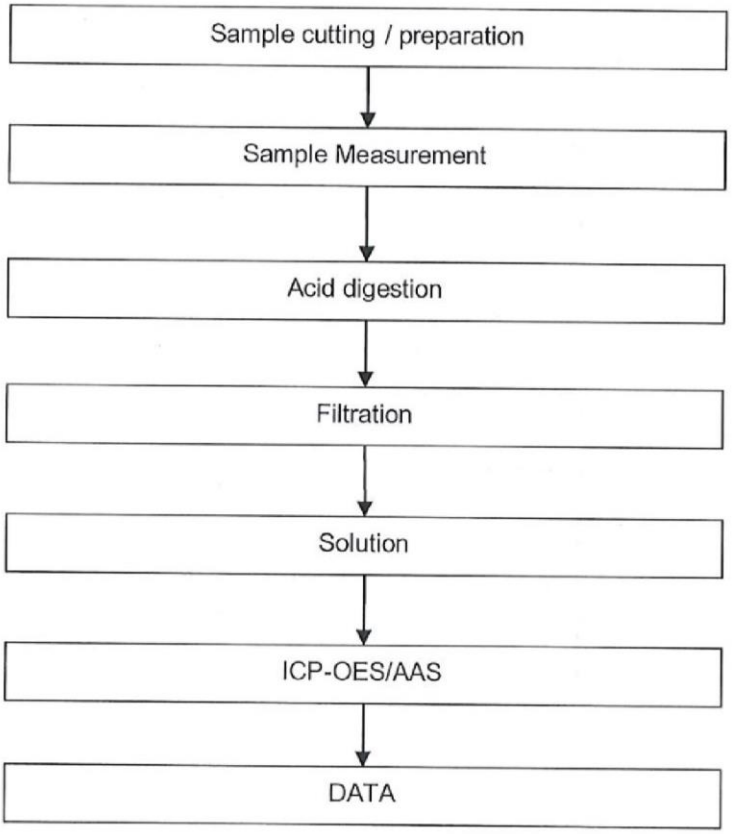


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Elementary Testing Flow Chart



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Sample photo:



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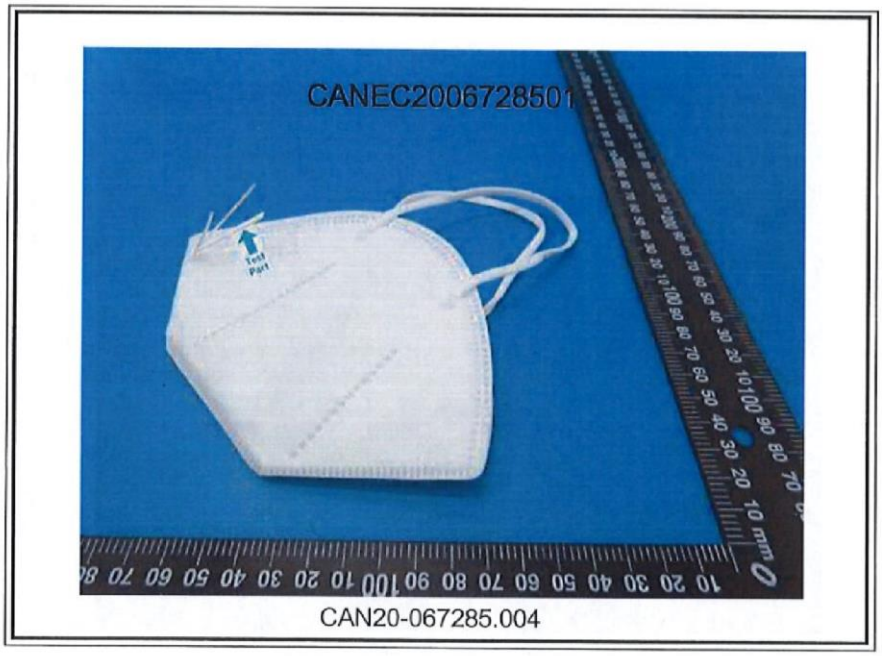
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