Test Report

Report No.: VIC20200320-ZYX35-CE-M

Applicant: NINGBO YIXIN INTELLINGENTIZED SCIENCE AND TECHNOLOGY CO.,LTD.

Product: Disposable Protective Face Mask

Standard(s): EN 14683:2019+AC:2019

VIC TESTING AND CERTIFICATION LTD

VIC TESTING AND CERTIFICATION LTD

TEST REPORT
EN 14683:2019+AC:2019
Medical face masks
Requirements and test methods

Report Number.....:	VIC20200320-ZYX35-CE-M
Tested by (name + signature).....:	Peter Chen
Approved by (+ signature).....:	David Zhang
Date of issue.....:	2020-03-20
Total number of pages.....:	17
Name of Testing Laboratory preparing the Report.....:	VIC TESTING AND CERTIFICATION LTD
Address.....:	CHASE BUSINESS CENTRE (CHD) 39-41 CHASE SIDE LONDON, N14 5BP, U.K
Applicant's name.....:	NINGBO YIXIN INTELLINGENTIZED SCIENCE AND TECHNOLOGY CO.,LTD.
Address.....:	No.26 Shangqiao Road,Xiwu Science Park,Fenghua,Ningbo, China
Manufacturer's name.....:	NINGBO YIXIN INTELLINGENTIZED SCIENCE AND TECHNOLOGY CO.,LTD.
Address.....:	No.26 Shangqiao Road,Xiwu Science Park,Fenghua,Ningbo, China
Test specification:	
Standard.....:	EN 14683:2019+AC:2019
Test procedure.....:	CE
Non-standard test method.....:	-
Test item description.....:	Disposable Protective Face Mask
Trade Mark.....:	-
Model/Type reference.....:	17.5cm*9.5cm ; 11.5cm*8.5cm

Summary of testing:

Tests performed (name of test and test clause):

Full tests of the following standard:

- EN 14683:2019+AC:2019

The submitted samples were found to comply with the requirements of above standards.

Possible test case verdicts:

- test case does not apply to the test object.....: N/A

- test object does meet the requirement.....: P (Pass)

- test object does not meet the requirement.....: F (Fail)

General remarks:

Throughout this report a ☒ comma / ☐ point is used as the decimal separator.

General product information:

The product is intended to be used as medical face masks intended to limit the transmission of infective agents from staff to patients during surgical procedures and other medical settings with similar requirements.

Model difference: all models are made of the same material, only the appearance size is different

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
4	**Classification**		P
	Medical face masks specified in this European Standard are classified into two types (Type I and Type II) according to bacterial filtration efficiency whereby	☒Type I ☐Type II ☐Type IIR	P
	Type II is further divided according to whether or not the mask is splash resistant.	Type I	N/A
	The 'R' signifies splash resistance.		N/A
5	**Requirements**		P
5.1	General		P
5.1.1	Materials and construction		P
	The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric.	Filter layer composed.	P
	The medical face mask shall not disintegrate, split or tear during intended use.	Not disintegrate, split or tear.	P
	In the selection of the filter and layer materials, attention shall be paid to cleanliness.	Cleanliness has been considered.	P
5.1.2	Design		P
	The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides.		P
	Medical face masks may have different shapes and constructions as well as additional features such as a face shield (to protect the wearer against splashes and droplets) with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours).		P
5.2	Performance requirements		P
5.2.1	All tests shall be carried out on finished products or samples cut from finished products.	Carried out on finished product.	P
5.2.2	Bacterial filtration efficiency (BFE)	Type I; ≥ 95 %	P
	When tested in accordance with Annex B, the BFE of the medical face mask shall conform to the minimum value given for the relevant type in Table 1.	BFE was tested in accordance with Annex B.	P
	For thick and rigid masks such as rigid duckbill or cup masks the test method may not be suitable as a proper seal cannot be maintained in the cascade impactor.		
	In these cases, another valid equivalent method shall be used to determine the BFE.		

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
	When a mask consists of two or more areas with different characteristics or different layer composition, each panel or area shall be tested individually.		
	The lowest performing panel or area shall determine the BFE value of the complete mask.		
5.2.3	Breathability	Type I; < 40 Pa/cm^2	P
	When tested in accordance with Annex C, the differential pressure of the medical face mask shall conform to the value given for the relevant type in Table 1.	Breathability was tested in accordance with Annex C.	P
	If the use of a respiratory protective device as face mask is required in an operating theatre and/or other medical settings, it might not fulfil the performance requirements with regard to differential pressure as defined in this European Standard.		N/A
	In such case, the device should fulfil the requirement as specified in the relevant Personal Protective Equipment (PPE) standard(s).		P
5.2.4	Splash resistance	Type I; Not required.	N/A
	When tested in accordance with ISO 22609 the resistance of the medical face mask to penetration of splashes of liquid shall conform to the minimum value given for Type IIR in Table 1.		N/A
5.2.5	Microbial cleanliness (Bioburden)	Type I, ≤ 30 cfu/g	P
	When tested according to EN ISO 11737-1 the bioburden of the medical mask shall be ≤ 30 cfu/g tested.	Bioburden was tested according to EN ISO 11737-1. Bioburden of the medical mask ≤ 30 cfu/g	P
	EN ISO 11737-1 specifies requirements and provides guidance for the enumeration and microbial characterisation of the population of viable microorganisms on or in a medical device, component, raw material or package.		P
	To determine the mask's bioburden according to EN ISO 11737-1:2018, refer to the procedure as described in Annex D.	Test is in accordance with Annex D.	P
	The number of masks that shall be tested is minimum 5 of the same batch/lot.		P
	Other test conditions as described in EN ISO 11737-1:2018 may be applied.	In accordance with EN ISO 11737-1:2018.	P
	In the test report, indicate the total bioburden per individual mask and based on the mask weight, the total bioburden per gram.		P

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
5.2.6	Biocompatibility	In accordance with EN ISO 10993-1.	P
	According to the definition and classification in EN ISO 10993-1, a medical face mask is a surface device with limited contact.		P
	The manufacturer shall complete the evaluation of the medical face mask according to EN ISO 10993-1 and determine the applicable toxicology testing regime.	In accordance with EN ISO 10993-1.	P
	The results of testing should be documented according to the applicable parts of the EN ISO 10993 series.		P
	The test results shall be available upon request.		P
	As a minimum, EN ISO 10993-5 and EN ISO 10993-10 shall be considered. 5.2.7 Summary of performance requirements		P
5.2.7	Summary of performance requirements	Type I: a Bacterial filtration efficiency (BFE): ≥ 95%; b Differential pressure: < 40 Pa/cm^2; c Splash resistance pressure: Not required; d Microbial cleanliness: ≤ 30 cfu/g.	P

Table 1 - Performance requirements for medical face masks

Test	Type I[a]	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm^2)	< 40	< 40	< 60
Splash resistance pressure (kPa)	Not required	Not required	≥ 16,0
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30

a Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations.
Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

6	**Labelling and information to be supplied**		P
	Annex I, §13, of the Medical Devices Directive (93/42/EEC) specifies the information that has to be specified on the packaging in which the medical face mask is supplied.		P
	The following information shall be supplied in addition:		P

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
	a).... umber of this European Standard;	EN 14683:2019+AC:2019	P
	b).... type of mask (as indicated in Table 1).	Type I	P
	EN ISO 15223-1 and EN 1041 should be considered.		P

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
A	**Information for users**		P
	When breathing, speaking, coughing, sneezing etc., one releases smaller or larger amounts of droplets of secretions from the mucous membranes in the mouth and nose.		P
	The majority of the nuclei are between 0,5 µm and 12 µm in diameter and especially the larger droplets can contain micro-organisms from the source site.	Nuclei: 0,5 µm - 12 µm.	P
	Nuclei can subsequently spread through the air to a susceptible site such as an open operating wound or sterile equipment.		P
	The medical face masks intended to be used in operating rooms and health care settings with similar requirements are designed to protect the entire working environment.	It was designed to protect the entire working environment.	P
	This standard describes two types of medical face masks with associated protection levels.	Type I medical face mask.	P
	As a minimum, Type I medical face masks are used for patients in order to reduce the risk of the spread of infections, particularly in epidemic or pandemic situations.	Type I medical face mask.	P
	Type II masks are principally intended for use by healthcare professionals in an operating room or other medical settings with similar requirements.		P
	A special case, also covered by the European Medical Devices legislation, is that in which the wearer wishes to protect him/herself against splashes of potentially contaminated fluids and particles that are created in the surgical environment, e.g. by the use of electro-cautery devices.		P
	If the intended use of the mask is to protect the wearer against infective agents (bacteria, viruses or fungi), the use of a respirator device should be considered.		N/A
	Performance requirements for respirators are the scope of EN 149.	In accordance with EN 149.	P
	The level of efficiency offered by a mask depends on a number of factors such as the filtration efficiency, quality of the material and the fit of the mask on the wearer's face.		P
	Different designs are suited for different applications and the careful choice of mask is therefore important in order to achieve the desired result.		P
	The filtration capacity of mask materials can vary depending on the filter media.		P

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
	The fit of masks varies considerably from those which are held in place by ear loops fastened behind the wearer's ears to those with tie bands around the head and a nose clamp that can be shaped to the wearer's nose.	Can be shaped to the wearer's nose.	P
	The effect of a very good or less good fit can be tested in vivo whereas the filtration efficiency may be reproducibly tested in vitro.	Effect can be tested in vivo.	P
	The considerable variations in results when masks are tested in vivo results in the need for large groups of test subjects and observations.	No any variations.	N/A
	It is thus usual to characterise mask performance using in vitro tests of the material from which the mask is made.		P
	It is, however, important to consider the fit of the mask carefully when a mask for a certain application is chosen. Users should request such information from their suppliers.		P
	A further factor to be considered is the capacity of the mask to absorb moisture from the exhaled air and thereby to maintain its performance over a longer period of time.		P
	The more advanced designs easily maintain their performance throughout even very long operations whereas the less advanced ones are intended only for short procedures.		P
	The contamination risk resulting from hand contact with a used mask means that it is essential that the mask is taken off and disposed of when no longer worn over nose and mouth.	No longer worn over nose and mouth.	P
	When there is a further need for protection then a new mask should be put on.	No further need for protection.	N/A
	Touching a used face mask or putting on a new one should always be followed by a full hand disinfection procedure and a used mask should always be disposed of when no longer needed or between two procedures.		P
	In summary, to use an appropriate mask is an effective means to protect the working environment from droplet contamination from nose and throat during health care procedures.		P
	Masks with very different performance are, however, available.	Without very different performance.	N/A
	Therefore such factors as infection risk and mask fit should be carefully considered when choosing a mask.		P

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
B	**Method for in-vitro determination of bacterial filtration efficiency (BFE)**		P
	WARNING:		P
	•..... Staphylococcus aureus is a pathogen.		P
	•..... The relevant national provisions by law and hygienic instructions when dealing with pathogens shall be complied with.		P
B.1	Principle		P
	A specimen of the mask material is clamped between a six-stage cascade impactor and an aerosol chamber.		P
	An aerosol of Staphylococcus aureus is introduced into the aerosol chamber and drawn through the mask material and the impactor under vacuum.		P
	The bacterial filtration efficiency of the mask is given by the number of colony forming units passing through the medical face mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol.		P
B.2	Reagents and materials		P
B.2.1	General		P
	B.2.2 and B.2.3 describe commercially available solutions of tryptic soy agar and tryptic soy broth.		P
	Other variants may be suitable.		P
B.2.2	Tryptic soy agar		P
	Formula/liter:		P
	•..... Enzymatic digest of casein.....:	15 g	P
	•..... Enzymatic digest of soybean meal..... :	5 g	P
	•..... Sodium chloride..... :	5 g	P
	•..... Agar..... :	15 g	P
	•..... Final pH..... :	7,3 ± 0,2 at 25 °C	P
B.2.3	Tryptic soy broth		P
	Formula/liter		P
	•..... Enzymatic digest of casein.....:	17 g	P
	•..... Enzymatic digest of soybean meal..... :	3 g	P
	•..... Sodium chloride..... :	5 g	P
	•..... Dipotassium phosphate..... :	2,5 g	P
	•..... Dextrose..... :	2,5 g	P
	•..... Final pH..... :	7,3 ± 0,2 at 25 °C	P

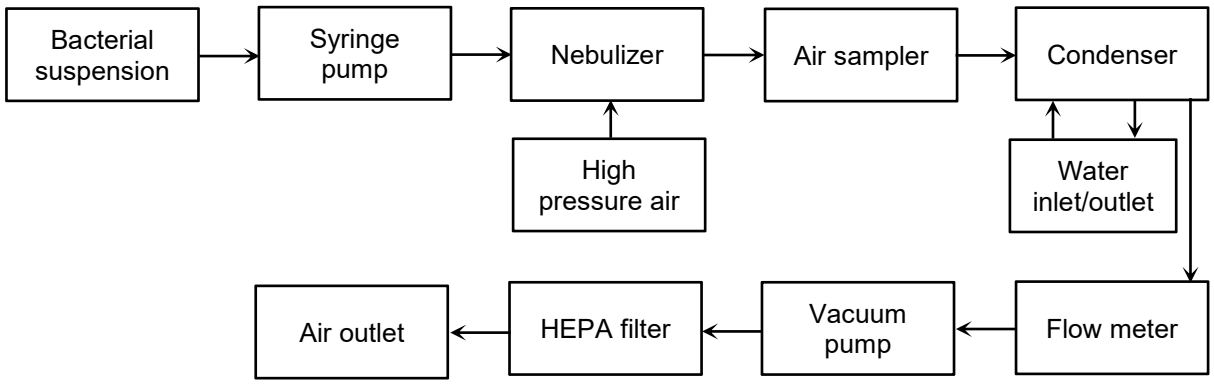
EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
B.2.4	Peptone water		P
	Formula/liter		P
	•..... Peptone..... :	10 g	P
	•..... Sodium chloride..... :	5 g	P
	•..... Final pH..... :	7,2 ± 0,2 at 25 °C	P
B.2.5	Culture of Staphylococcus aureus ATCC 6538, growing on tryptic soy agar slants		P
B.3	Apparatus		P
B.3.1	Six stage cascade impactor		P
B.3.2	Nebulizer, capable of delivering particles with a mean size of (3,0 ± 0,3) µm when in contact with the impactor	3,1 µm	P
B.3.3	Aerosol chamber, glass, 600 mm long and 80 mm in external diameter	Long: 600 mm; Diameter: 80 mm.	P
B.3.4	Flow meters, capable of measuring a flow rate of 28,3 l/min	Flow rate: 28,3 l/min.	P
B.3.5	Pressure gauge, capable of measuring a pressure of 35 kPa to an accuracy of ± 1 kPa	35 kPa	P
B.3.6	Erlenmeyer flasks, 250 ml and 500 ml capacity		P
B.3.7	Peristaltic or syringe pump, capable of delivering 0,01 ml/min	0,01 ml/min	P
B.3.8	Vacuum pump, capable of maintaining a flow rate of 57 l/min	Flow rate: 57 l/min.	P
B.4	Test specimens		P
	Test specimens shall be cut from complete masks.		P
	Each specimen shall be minimum 100 mm by 100 mm and shall include all layers of the mask in the order in which they are placed in the complete mask.		P
	The number of specimens that shall be tested is minimum 5 (five), but can be greater and shall be increased if necessary to allow for an AQL of 4 %.	5 specimens	P
	All specimens tested shall be taken from representative areas to incorporate all/any variation in construction.		P
	Unless otherwise specified, the testing shall be performed with the inside of the medical face mask in contact with the bacterial challenge.		P
	Each test specimen shall be conditioned at (21 ± 5) °C and (85 ± 5) % relative humidity for the time required to bring them into equilibrium with atmosphere prior to testing.		P

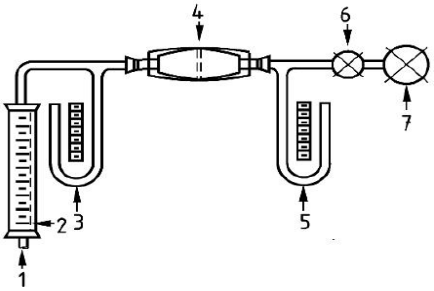
EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
B.5	Preparation of bacterial challenge		P
	Staphylococcus aureus (see B.2.4) shall be inoculated into 30 ml tryptic soy broth in an Erlenmeyer flask and incubated with mild shaking at a temperature of (37 ± 2) °C for (24 ± 2) h.	37 °C for 24 h.	P
	The culture shall then be diluted in peptone water to give a concentration of approximately 5×10^5 cfu/ml.	5×10^5 cfu/ml	P
	The bacterial challenge shall be maintained at (2 200 ± 500) cfu per test.	2300 cfu	P
	The bacterial challenge shall be determined on the basis of experience and previous positive control plates (see B.6.3) and the dilution of the challenge suspension adjusted accordingly.		P
	The mean particle size in the bacterial challenge shall be maintained at (3,0 ± 0,3) µm (see B.6.9).	3,1 µm	P
B.6 B.6.1	Procedure		P
	Assemble the apparatus in accordance with the flow chart shown in Figure B.1.		P
B.6.2	Deliver the bacterial challenge to the nebulizer using the peristaltic or syringe pump.		P
B.6.3	Perform a positive control run without a test specimen. Initiate the bacterial challenge by turning on the vacuum pump and adjust the flow rate through the cascade impactor to 28,3 l/min.	Flow rate: 28,3 l/min.	P
	Deliver the bacterial challenge for 1 min.		P
	Maintain the airflow through the impactor for 2 min.	2 min	P
	Then remove the plates from the impactor.		P
	Ensure that each plate is numbered to indicate its position in the impactor.		P
B.6.4	Place fresh plates in the impactor, fix a test specimen in place and repeat the above procedure.		P
B.6.5	Repeat this procedure for each test specimen.		P
B.6.6	After the last test specimen has been tested, perform a further positive control run.		P
B.6.7	Perform a negative control run by passing air, without addition of the bacterial challenge, through the cascade impactor for 2 min.	2 min	P
B.6.8	Incubate all the plates at (37 ± 2) °C for (48 ± 4) h.	37 °C for 48 h.	P

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
B.6.9	For each specimen and control run, count the number of colonies on each plate and add up the counts to give the total number of cfu collected by the impactor using the “positive hole” conversion table1) in accordance with the instructions of the cascade impactor manufacturer (stages 3 to 6).		P
	For the two positive control runs, take the mean of the two totals.		P
	From the positive control plates calculate the mean particle size of the bacterial challenge aerosol using the “positive hole” conversion table in accordance with the instructions of the cascade impactor manufacturer.		P
B.7	Calculation of bacterial filtration efficiency		P
	For each test specimen calculate the bacterial filtration efficiency B, as a percentage, using the formula.....:	B = (C − T) / C × 100 C is the mean of the total plate counts for the two positive control runs; T is the total plate count for the test specimen.	P
B.8	Test report	a number and date of this European Standard; b lot number or batch code of the masks tested; c dimensions of the test specimens and the size of the area tested; d which side of the test specimen was facing towards the challenge aerosol; e flow rate during testing; f mean of the total plate counts of the two positive controls; g mean plate count of the negative controls; h bacterial filtration efficiency for each test specimen.	P

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict

Principle of BFE test apparatus



EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
C	**Method for determination of breathability (differential pressure)**		P
C.1	Principle		P
	A device which measures the differential pressure required to draw air through a measured surface area at a constant air flow rate is used to measure the air exchange pressure of the medical face mask material, as shown in Figure C.1. 		P
	Water-filled manometers (M1 and M2) are used to measure the differential pressure.		P
	A flow meter is used for measurement of the airflow.		P
	An electric vacuum pump draws air through the apparatus and a needle valve is used to adjust the airflow rate.		P
C.2	Apparatus		P
C.2.1	Flow meter, capable of measuring an airflow of 8 l/min	Airflow: 8 l/min.	P
C.2.2	Manometers, M1 and M2 or differential manometer		P
C.2.3	Electric vacuum pump		P
C.2.4	Valve		P
C.3	Test specimens		P
	Test specimens are complete masks or shall be cut from masks.	Complete mask.	P
	Each specimen shall be able to provide 5 different circular test areas of 2,5 cm in diameter.	Diameter: 2,5 cm	P
	If one specimen cannot provide 5 test areas of 2,5 cm in diameter, the number of test areas retrieved should be representative for the entire mask.	Diameter: 2,5 cm	P
	The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL of 4 %.	5 specimens	P
	All specimens tested shall be taken from areas representative from the mask to incorporate all/any variation in construction.		P

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
	Each test specimen shall be conditioned at (21 ± 5) °C and (85 ± 5) % relative humidity for the time required to bring them into equilibrium with atmosphere prior to testing.	(21 ± 2) °C; (85 ± 2) %	P
C.4	Procedure		P
C.4.1	The test specimen is placed across the 2,5 cm diameter orifice (total area 4,9 cm^2) and clamped into place so as to minimise air leaks and that the tested area of the specimen will be in line and across the flow of air.	Area: 4,9 cm^2	P
C.4.2	The pump is started and the flow of air adjusted to 8 l/min.		P
C.4.3	The manometers M1 and M2 are read and recorded.		P
C.4.4	The procedure described in steps C.4.1 through C.4.3 is carried out on 5 (or appropriate number of) different areas of the mask and the readings averaged.		P
C.5	Calculation of differential pressure		P
	For each test specimen calculate the differential pressure ΔP as.....:	ΔP = (Xm1 – Xm2)/4,9	P
C.6	Test report	a number and date of this European Standard; b lot number or batch code of the masks tested; c flow rate during testing; d differential pressure for each test specimen.	P

ZA	**Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices**		P
	This European Standard has been prepared under a mandate given to CEN by the European Commission Union to provide a means of conforming to the essential requirements of New Approach EU Directive 93/42/EEC concerning medical devices.		P
	Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.		P

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
ZA.1	Correspondence between this European Standard and EU Directive 93/42/EEC concerning medical devices		P
	Clause/subclause of this European Standard; 5.1.1, 5.1.2, 5.2.1, 5.2.2, 5.2.3, 6.....:	Corresponding Essential Requirement of Directive 93/42/EEC: 8.1	P
	Clause/subclause of this European Standard; 5.2.2..... :	Corresponding Essential Requirement of Directive 93/42/EEC: 9.2	P
	Clause/subclause of this European Standard; 6....:	Corresponding Essential Requirement of Directive 93/42/EEC: 13	P
	WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.		P

Photo document

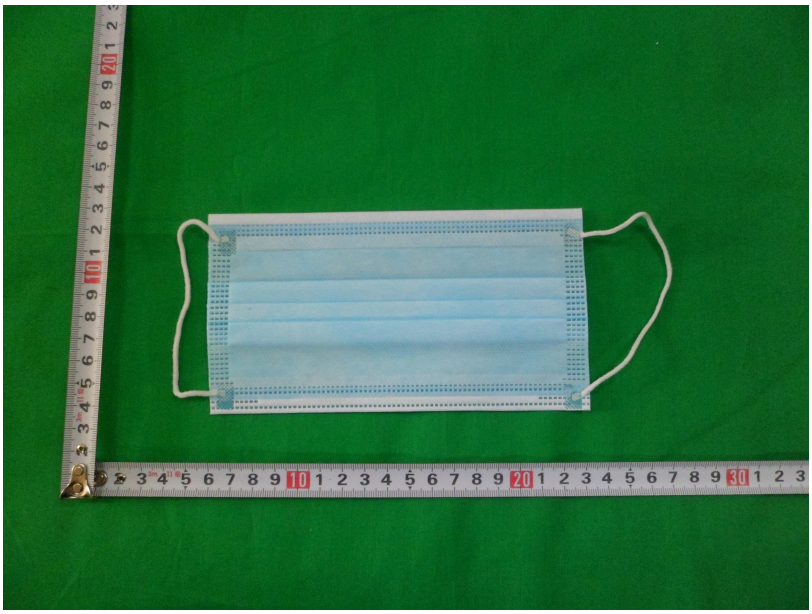


Fig. 1 Overview

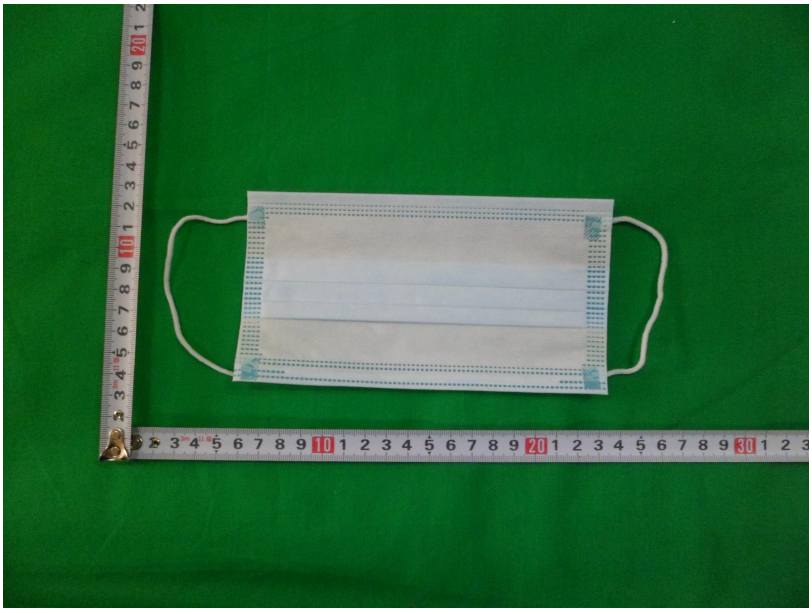


Fig. 2 Overview

--- End of report ---

VIC TESTING AND CERTIFICATION LTD

Add：CHASE BUSINESS CENTRE (CHD) 39-41 CHASE SIDE LONDON, N14 5BP, U.K