MASQUE CHIRURGICAL - TYPE II

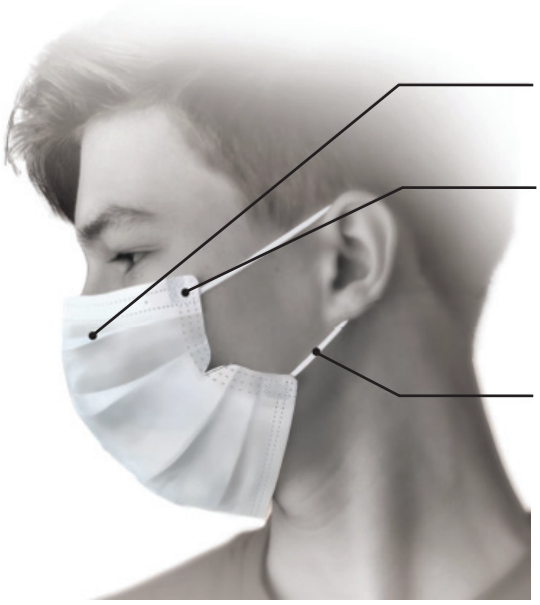
PRÉVENIR LA CONTAMINATION PAR LES VOIES RESPIRATOIRES

En partenariat exclusif avec Iris Healthcare, fabricant nippon de masques depuis 2009. Iris possède 7 unités de production à travers le monde dont une chaîne ouvrira en Région Parisienne à l'automne 2020.

MASQUE À USAGE UNIQUE

Avec une Efficacité de Filtration Bactérienne (EFB) supérieure ou égale à 98%, le masque à usage unique a une double fonction :

- prévenir la contamination du patient et de son environnement, des micro-organismes exhalés par le soignant.
- Quand il est porté par le patient contagieux, prévenir le risque de contamination de son entourage et de son environnement.



Masque constitué de trois couches de polypropylène.

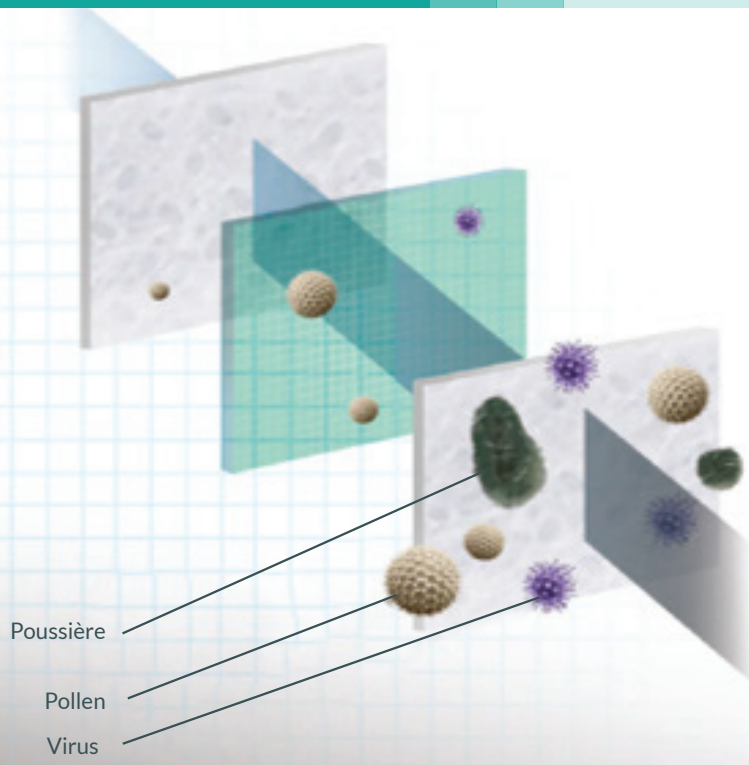
Chaque côté du masque dispose d'une fixation auriculaire élastique.

Extrêmement léger pour un port confortable.

FILTRATION EFFICACE

CARACTÉRISTIQUES TECHNIQUES :

- Trois couches en polypropylène.
- Élastique de fixation : polyuréthane, polyester.
- Barrette nasale : polyéthylène.
- Coloris : blanc.
- Sans entretien, dispositif à usage unique 4h d'utilisation.
- Durée de conservation : 2 ans
- Conditionnement : 50 masques.
- Conformité : EN14683:2019 type II.
- EFB (Efficacité de Filtration Bactérienne) égale ou supérieure à 98%.
- Sans latex.
- Sans fibre de verre.
- Une structure en triple épaisseur assurant la filtration de corps étrangers allant de 0.1 µm à 3 µm.
- Propreté microbiologique < 30 ufc/g.
- Pression différentielle :ΔP < 40 Pa.



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IRIS OHYAMA FRANCE SAS

Déclaration de Conformité UE

Nous, Société IRIS OHYAMA, 990 avenue Marguerite Perey 77127 Lieusaint déclarons sous notre seule responsabilité que le produit:

Marque : IRIS OHYAMA

Nom commercial : MASQUE CHIRURGICAL TYPE II

Références: PN-W-L-50P EAN13 8716382204296

PN-W-L-7P EAN13 8716382204289

Auquel se réfère cette déclaration est conforme aux exigences essentielles et aux autres dispositions de la Directive Médicale Européenne 93/42/CEE qui lui sont applicables.

Le produit est en conformité avec la norme suivante : EN 14683:2019

TYPE II / EFB microbiologique > 98% /- DISPOSITIF MEDICAL CLASSE 1– CE

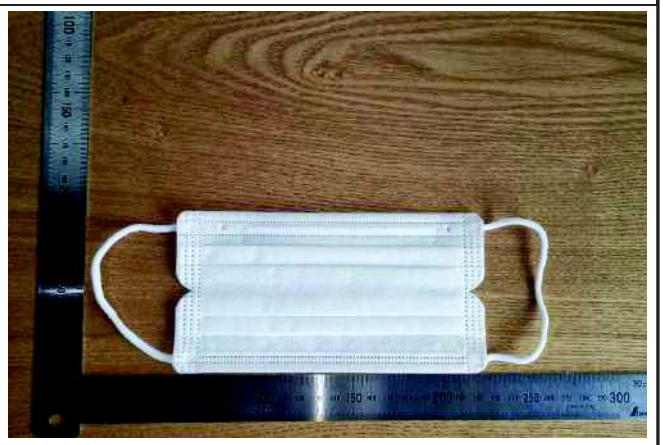
A Lieusaint , le 27 mai 2020

Yasushi OYAMA
Directeur Général

IRIS OHYAMA FRANCE
Société Unipersonnelle 10 000 000€
990 Avenue Marguerite Perey
77127 Lieusaint France
RCS de Melun 829 144 161 – APE 2229B

Prüfbericht-Nr.: *Test Report No.*:	**60366839 001**	**Auftrags-Nr.:** *Order No.*:	**190125825**	Seite 1 von 15 *Page 1 of 15*
Kunden-Referenz-Nr.: *Client Reference No.*:	**N/A**	**Auftragsdatum:** *Order date*:	**2020-04-21**	

Auftraggeber: *Client*:	
Prüfgegenstand: *Test item*:	**DISPOSABLE MEDICAL FACE MASK**
Bezeichnung / Typ-Nr.: *Identification / Type No.*:	**PN-W-L-7P**
Auftrags-Inhalt: *Order content*:	**Type test**
Prüfgrundlage: *Test specification*:	**EN 14683:2019+AC:2019(except for Clause 5.2.6 Biocompatibility)**
Wareneingangsdatum: *Date of receipt*:	**2020-04-11**
Prüfmuster-Nr.: *Test sample No.*:	**Engineering sample**
Prüfzeitraum: *Testing period*:	**2020-04-11 to 2020-04-22**
Ort der Prüfung: *Place of testing*:	**See page 3**
Prüflaboratorium: *Testing laboratory*:	**TÜV Rheinland (China) Ltd.**
Prüfergebnis*: *Test result**:	**Pass**



geprüft von / *tested by*: Mongdi Zhang

2020-05-14 Zhang Mengdi / Project Engineer

Datum *Date*	**Name / Stellung** *Name / Position*	**Unterschrift** *Signature*

kontrolliert von / *reviewed by*: Han Dong

2020-05-14 Han Dong / Reviewer

Datum *Date*	**Name / Stellung** *Name / Position*	**Unterschrift** *Signature*

Sonstiges / *Other*:

The test report consists of EN 14683 test report including this cover page (15 pages).

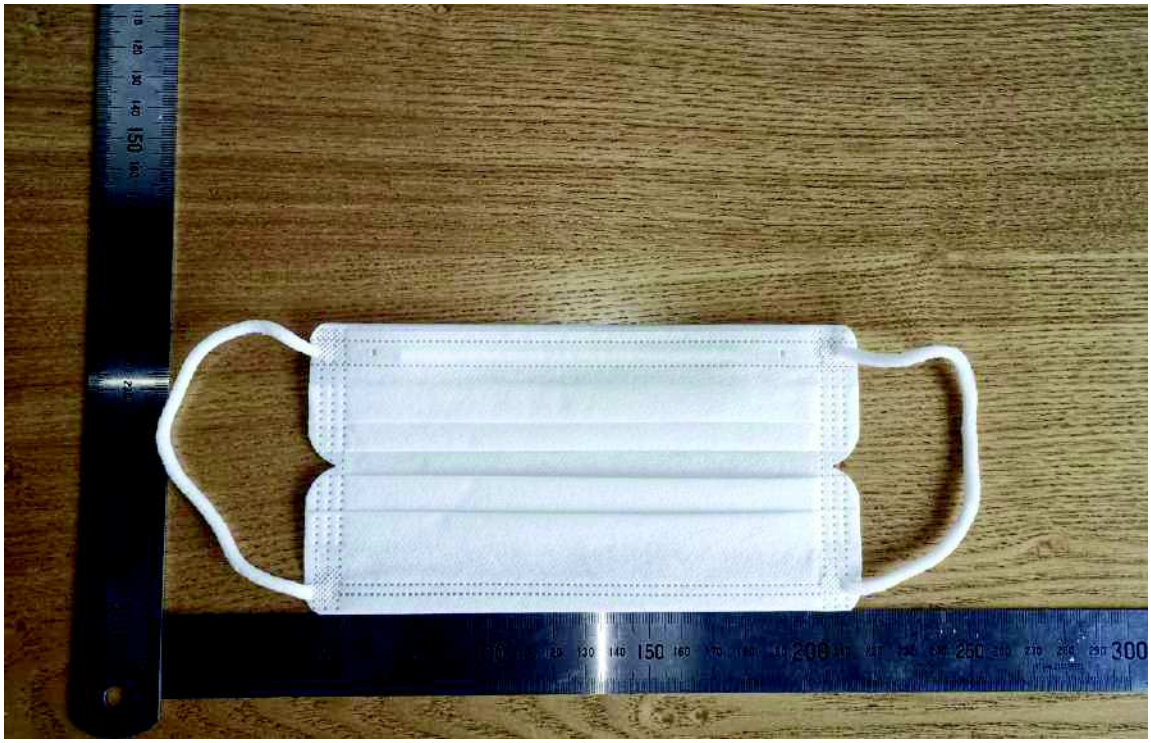
Clause 5.2.6 Biocompatibility is not evaluated in this report.

Zustand des Prüfgegenstandes bei Anlieferung: Prüfmuster vollständig und unbeschädigt
Condition of the test item at delivery: *Test item complete and undamaged*

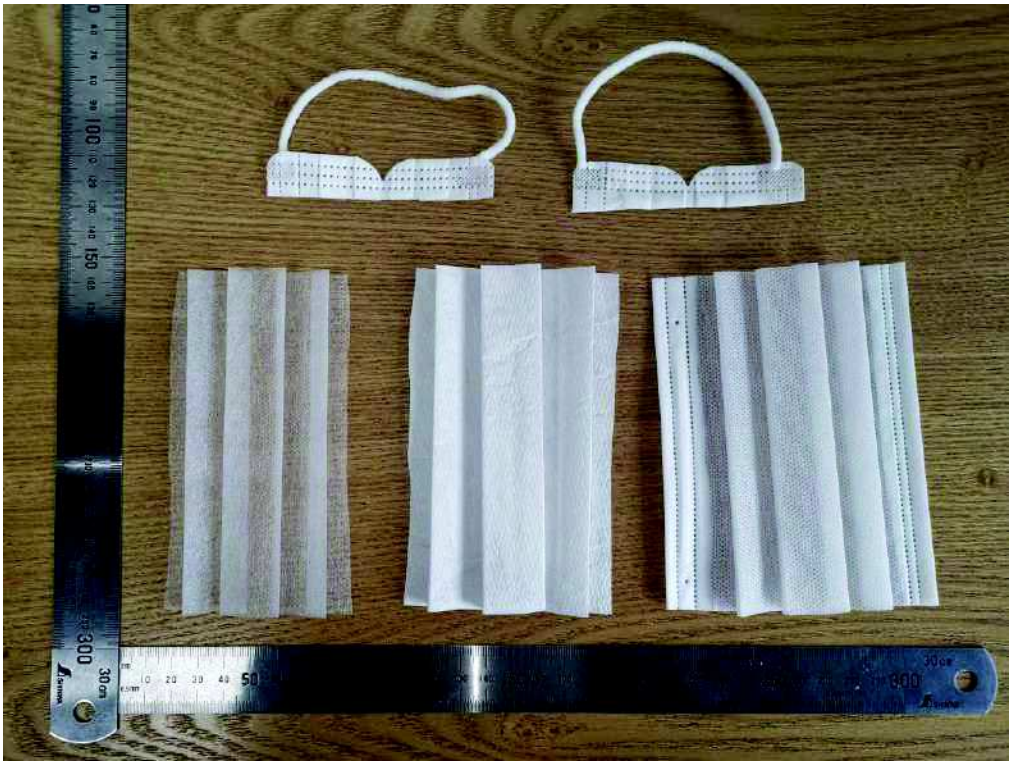
* Legende:	1 = sehr gut	2 = gut	3 = befriedigend	4 = ausreichend	5 = mangelhaft
	P(ass) = entspricht o.g. Prüfgrundlage(n)		F(ail) = entspricht nicht o.g. Prüfgrundlage(n)	N/A = nicht anwendbar	N/T = nicht getestet
Legend:	*1 = very good*	*2 = good*	*3 = satisfactory*	*4 = sufficient*	*5 = poor*
	P(ass) = passed a.m. test specification(s)		*F(ail) = failed a.m. test specification(s)*	*N/A = not applicable*	*N/T = not tested*

Front view of face mask:

Back view of face mask:



Open view of face mask:



Date of receipt of test item(s) .....:	See cover page
Dates of tests performed .....:	See cover page

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 was not evaluated for the requirement .... :	N/E (collateral standards only)
- test object does not meet the requirement ..... :	F (Fail)

General remarks:

"(See Attachment #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.
The tests results presented in this report relate only to the object tested.
This report shall not be reproduced except in full without the written approval of the testing laboratory.
List of test equipment must be kept on file and available for review.
Additional test data and/or information provided in the attachments to this report.

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

Name and address of factory (ies) ..... :

General product information:

The submitted samples are type II, DISPOSABLE MEDICAL FACE MASK which is intended to be worn to protect against the spread or transmission of infectious germs during surgical interventions in operating theatres and other medical facilities. The main aim is to protect the patient against infectious germs. It is a non-sterile product.

Clause 5.2.6 Biocompatibility is not evaluated in this test report.

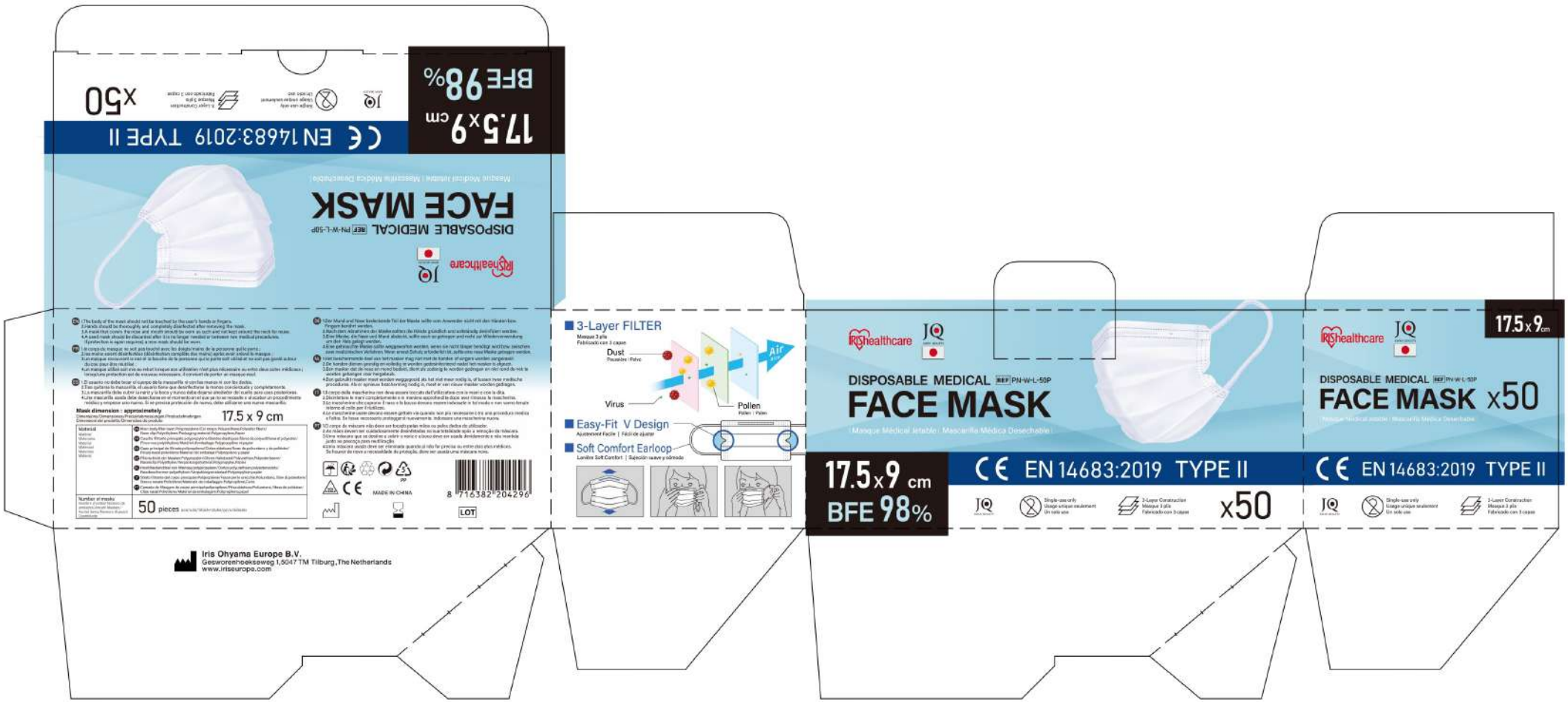
The test results are for reference only. Relevant certification may be needed if the mask is intended to be sold in Europe.

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 II is further divided according to whether or not the mask is splash resistant. The 'R' signifies splash resistance.	Type II	P
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.	Polypropylene, Polyurethane, Polyester fibers, Polyethylene	P
	The medical face mask shall not disintegrate, split or tear during intended use.	Complied	P
	In the selection of the filter and layer materials, attention shall be paid to cleanliness.	Complied	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.	Fitted closely over nose.	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).	With nose clip.	P
5.2	**Performance requirements**		P
5.2.1	**General**		P
	All tests shall be carried out on finished products or samples cut from finished products.		P
5.2.2	**Bacterial filtration efficiency (BFE)**		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 1.1 1.2.	The Bacterial Filtration Efficiency ≥ 98% See appended Table 5.2.2	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.	Not such masks	N/A
	When a mask consists of two or more areas with different characteristics or different layer-composition, each panel or area shall be tested individually.		N/A

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
	The lowest performing panel or area shall determine the BFE value of the complete mask		N/A
5.2.3	**Breathability**		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 2.1 2.2.	The differential pressure <40 Pa/cm^2 See appended Table 5.2.3	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. In such case, the device should fulfil the requirement as specified in the relevant Personal Protective Equipment (PPE) standard(s).	No such respiratory protective device provided	N/A
5.2.4	**Splash resistance**		N/A
	When tested in accordance with ISO 22609:2004 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.	Not such masks	N/A
5.2.5	**Microbial cleanliness (Bioburden)**		P
	When tested according to EN ISO 11737-1:2018 the bioburden of the medical mask shall be ≤ 30 CFU/g tested (see Table 3.1 3.2).	The bioburden of the medical mask was ≤30 CFU/g See appended Table 5.2.5	P
5.2.6	**Biocompatibility**		N/E
	According to the definition and classification in EN ISO 10993-1:2009, a medical face mask is a surface device with limited contact.	Not evaluated in this test report.	N/E
	The manufacturer shall complete the evaluation of the medical face mask according to EN ISO 10993-1:2009 and determine the applicable toxicology testing regime.		N/E
	The results of testing should be documented according to the applicable parts of the EN ISO 10993 series.		N/E
	The test results shall be available upon request.		N/E
6	**Marking, labelling and packaging**		P
	Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the medical face mask is supplied.	Considered	P
	The following information shall be supplied:		P
	a) number of this European Standard;	EN 14683:2019 Marked on the label	P
	b) type of mask (as indicated in Table 1).	Type II Marked on the label	P
	EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered.	Compliance	P

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

5.2.2	**TABLE: Bacterial filtration efficiency (BFE)**							**P**
Batch/ lot no.:	**Test Speci -men no.:**	**Dimension of the test specimen L x W (mm x mm)**	**test area (cm^2)**	**Flow rate (l/min)**	**Mean of the total plate counts of the two positive controls**	**Mean plate count of the negative controls**	**BFE for each test specimen (%)**	**Remarks**
3200403104	**1**	100×100	100	28.3	2389	0	100.0	≥98
	2	100×100	100	28.3	2486	0	99.1	≥98
	3	100×100	100	28.3	2355	0	100.0	≥98
	4	100×100	100	28.3	2487	0	98.6	≥98
	5	100×100	100	28.3	2518	0	98.5	≥98
Supplementary information: 1, Each specimen was conditioned at (21 ± 5)°C and (85 ± 5)% relative humidity for 4h to bring them into equilibrium with atmosphere prior to testing. 2, The side of the test specimen was facing towards the challenge aerosol:out side of mask								


DISPOSABLE MEDICAL REF PN-W-L-50P
FACE MASK
Masque Médical Jetable | Mascarilla Médica Desechable
17.5 x 9 cm
BFE 98%
EN 14683:2019 TYPE II
x50
50 pieces
17.5 x 9 cm
3-Layer FILTER
Masque 3 plis
Fabricado con 3 capas
Dust
Poussière · Polvo
Virus
Pollen
Air
Easy-Fit V Design
Ajustement Facile | Fácil de ajustar
Soft Comfort Earloop
Lanière Soft Confort | Sujeción suave y cómoda
MADE IN CHINA
LOT
Iris Ohyama Europe B.V.
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www.iriseuropa.com