ORPHILA™

FFP2 Particle Filtering Half Mask

CE

AENOR

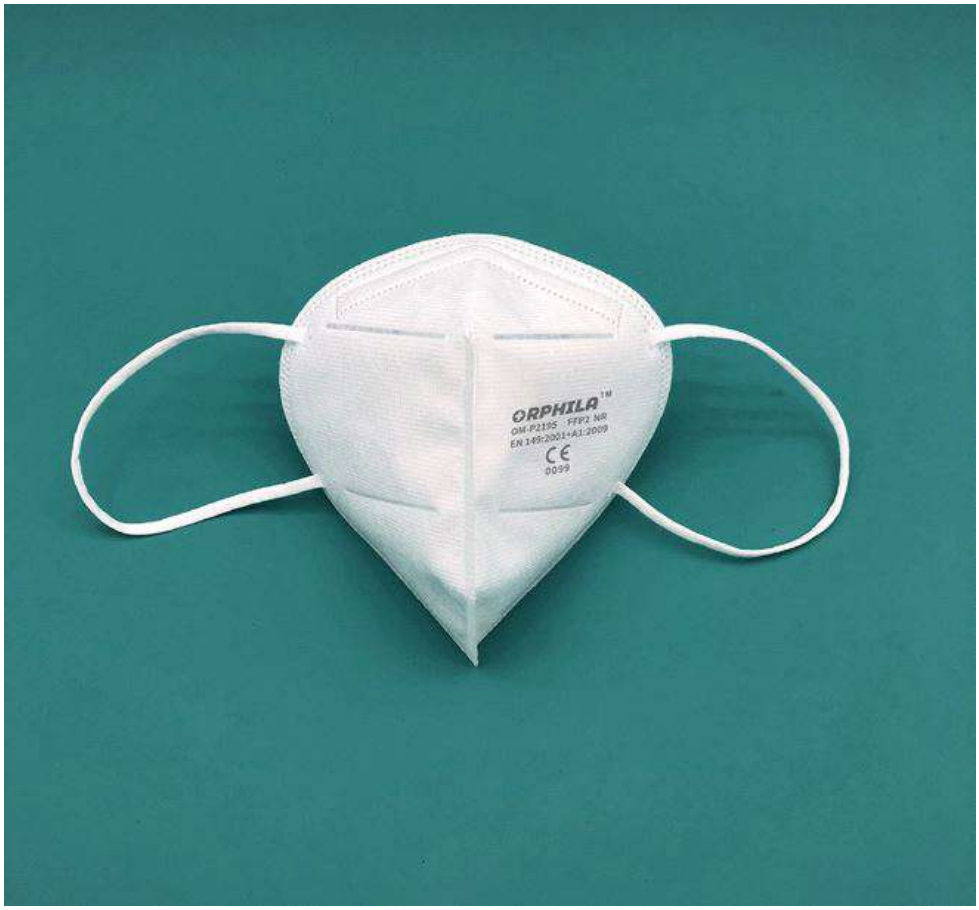
REACH NPS

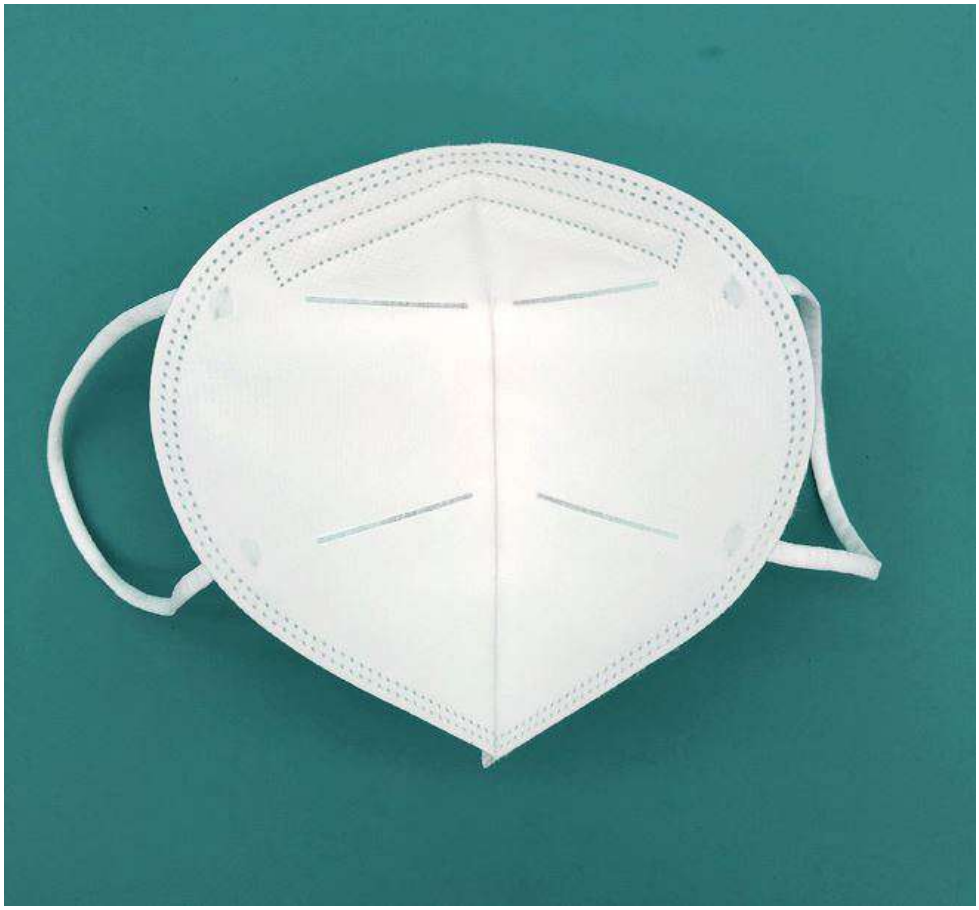
FFP2 NR
Model: OM-P2195

Meets EN149:2001+A1:2009 standard requirements.

CE Certificate No.A18/000037
TUV REACH No.178141074a 001

Product Photos



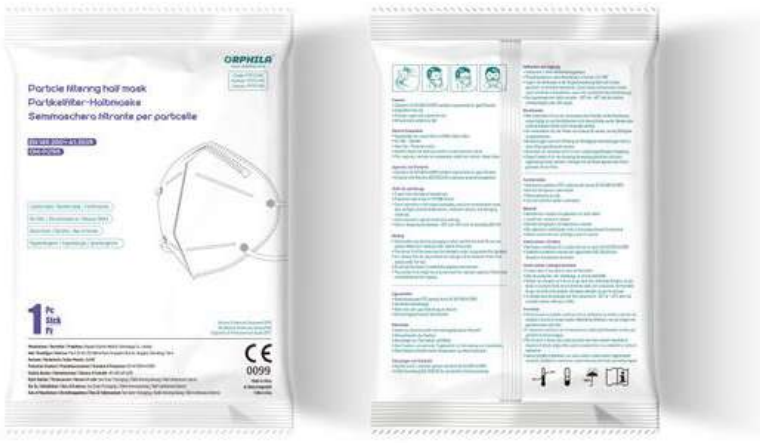


1. Detail of Package

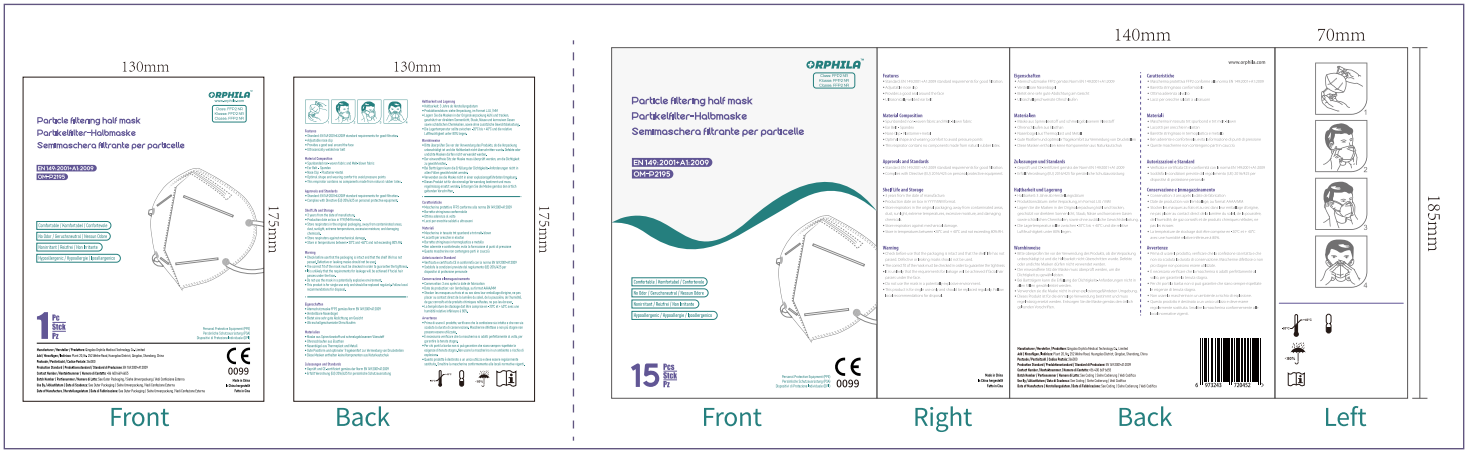
ORPHILA™

Packaging of OM-P2195

15 bag in box



Package Details	Bag Details		Carton Details		
1pc/bag，15bag/box, 99box/carton	130*175mm	G.W 0.17kg	790*590*450mm	1485pcs	G.W 16.3kg



With Edge Protector

BUREAU VERITAS
Certification

Qingdao Orphila Medical Technology Co., Limited

Rm0501, Futai Square No.18 Hongkong Middle Road, Qingdao, Shandong, China

Unified social credit code: 913702035990204532

Bureau Veritas Certification Holding SAS - UK Branch certifies that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the management system standards detailed below

ISO 9001:2015

Scope of certification

Design, Production and Sales of Masks,

Production and Sales of Melt-blown Cloth

Original cycle start date:	**10-07-2020**
Expiry date of previous cycle:	**NA**
Certification / Recertification audit date:	**NA**
Certification / Recertification cycle start date:	**10-07-2020**

Subject to the continued satisfactory operation of the organisation's Management System, this certificate expires on: **09-07-2023**

Certificate No. : **CNBJ322095-UK** Version: **No.1**, Revision date: **10-07-2020**

Signed on behalf of BVCH SAS UK Branch

UKAS MANAGEMENT SYSTEMS
0008

Certification body address: 5th Floor, 66 Prescot Street, London E1 8HG, United Kingdom
Local office address: F22, Tower B, Beijing Global Trade Center, 36 North Third Ring Road East, Dongcheng District, Beijing, China. 100013.

Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organisation.
To check this certificate validity please call: (+86 10 59683888)
Certified organisation has to accept and pass regular surveillance audits, then this certificate can be continuously valid. Information of this certificate may be obtained by visiting CNCA website (www.cnca.gov.cn).

AENOR

Certificado de Examen UE de Tipo
EU Type-Examination Certificate

A18/000037

AENOR, como organismo notificado (nº 0099) para el Reglamento (UE) 2016/425, ha emitido este certificado a favor de
In compliance with Regulation (EU) 2016/425, the notified body AENOR (nº 0099) has issued this certificate to

Qingdao Orphila Medical Technology Co., Limited

Domicilio social / Registered office	Room 501, Futai Square No.18 266000 Hongkong Middle Road, Qingdao, Shandong (China)
para el producto / for the product	Dispositivos de protección respiratoria. Medias máscaras filtrantes de protección contra partículas. / Respiratory protection devices. Half filter masks to protect against particles.
conforme con el Reglamento in compliance with Regulation	Reglamento UE 2016/425 de Equipos de Protección Individual (Regulation EU 2016/425 on Personal Protective Equipment)
Norma armonizada / Harmonized standard	EN 149:2001+A1:2009
	Más información en el anexo / See annex for more information.
Centro de producción / Production site	No. 252 Weihe Road, 266000 Huangdao District, Qingdao, Shandong, (China)
Esquema de evaluación Assessment scheme	Anexo V (Examen UE de Tipo – Módulo B) del Reglamento (UE) 2016/425. Annex V (EU Type-examination – Module B) of Regulation (EU) 2016/425.
	Este certificado anula y sustituye al A18/000037, de fecha 2020-06-22 This certificate supersedes A18/000037, dated 2020-06-22
Fecha de emisión / First issued on	2020-06-22
Fecha de modificación / Modified on	2020-07-09
Fecha de expiración / Validity date	2025-06-22

Rafael GARCÍA MEIRO
Director General / CEO

Original Electronic Certificate

AENOR INTERNACIONAL S.A.U.
Génova, 6. 28004 Madrid. España
Tel. 91 432 60 00.- www.aenor.com

Organismo de control acreditado por ENAC con acreditación Nº 1/C-PR354
Control body accredited by ENAC. Accreditation number 1/C-PR354

AENOR

Certificado de Examen UE de Tipo
EU Type-Examination Certificate

A18/000037

Anexo al Certificado
Annex to Certificate

Norma armonizada / Harmonized standard EN 149:2001+A1:2009

Marca Comercial / Trade Mark	Referencia / Reference	Clasificación / Classification	Descripción / Description
ORPHILA	OM-P2195	FFP2 NR	MEDIA MASCARILLA, DE CINCO CAPAS DE FILTRADO, DOS LAZOS FIJOS DE SUJECIÓN A OREJAS, DE TIPO PLEGABLE. DISEÑADA PARA PROTEGER CONTRA PARTÍCULAS SÓLIDAS O LÍQUIDAS SUSPENDIDAS EN EL AIRE. NO REUTILIZABLE / FILTERING HALF MASK, FIVE FILTERING LAYERS, TWO EARLOOPS, FOLDING STYLE. DESIGNED TO PROTECT AGAINST AIRBORNE SOLID OR LIQUID PARTICLES. NON-REUSABLE.

Fecha de emisión / First issued on 2020-06-22
Fecha de modificación / Modified on 2020-07-09
Fecha de expiración / Validity date 2025-06-22

Original Electronic Certificate

AENOR INTERNACIONAL S.A.U.
Génova, 6. 28004 Madrid. España
Tel. 91 432 60 00.- www.aenor.com

Organismo de control acreditado por ENAC con acreditación Nº 1/C-PR354
Control body accredited by ENAC. Accreditation number 1/C-PR354

AENOR

Certificado de Conformidad
Certificate of Conformity

CE
0099

A18/000174

AENOR, como organismo notificado (nº 0099) para el Reglamento (UE) 2016/425, ha emitido este certificado a favor de
In compliance with Regulation (EU) 2016/425, the notified body AENOR (nº 0099) has issued this certificate to

Qingdao Orphila Medical Technology Co., Limited

Domicilio social / Registered office	Room 501, Futai Square No.18 266000 Hongkong Middle Road, Qingdao, Shandong (China)
para aprobar el	Sistema de aseguramiento de la calidad del proceso de producción (módulo D)
in order to approve the	Quality assurance system of the production process (module D)
conforme con el in compliance with	Reglamento (UE) 2016/425, Anexo VIII Regulation (EU) 2016/425, Annex VIII
Referencias / References	Detalladas en el Anexo al Certificado / Specified in Annex to the Certificate
Centro de producción / Production site	No. 252 Weihe Road, 266000 Huangdao District, Qingdao, Shandong, (China)
Esquema de evaluación Assessment scheme	Este certificado se limita al sistema de aseguramiento de la calidad del proceso de producción para los equipos amparados por los certificados de examen UE de tipo detallados en el anexo a este Certificado y fabricados en el centro indicado más arriba. This certificate is exclusively limited to the quality assurance of the production process for personal protective equipment covered by the EU type-examination certificates detailed in annex to the present certificate and to the above mentioned production site.
	Este certificado anula y sustituye al A18/000174, de fecha 2020-09-16 This certificate supersedes A18/000174, dated 2020-09-16
Fecha de emisión / First issued on	2020-09-16
Fecha de modificación / Modified on	2020-11-17
Fecha de expiración / Validity date	2023-09-16

Rafael GARCÍA MEIRO
Director General / CEO

Original Electronic Certificate

AENOR INTERNACIONAL S.A.U.
Génova, 6. 28004 Madrid. España
Tel. 91 432 60 00.- www.aenor.com

Organismo de control acreditado por ENAC con acreditación Nº 1/C-PR354
Control body accredited by ENAC. Accreditation number 1/C-PR354

AENOR

Certificado de Conformidad
Certificate of Conformity

A18/000174

Anexo al Certificado
Annex to Certificate

Protección / Protection	Certificados UE de tipo cubiertos / EU type examination certificates covered	Organismo notificado emisor / Issuing notified body	Fecha Validez / Validity date	Prenda / Garment
RESPIRATORIA / RESPIRATORY	A18/000037	AENOR 0099	2025-06-22	MASCARILLA / MASK
RESPIRATORIA / RESPIRATORY	A18/000063	AENOR 0099	2025-08-04	MASCARILLA / MASK
RESPIRATORIA / RESPIRATORY	A18/000064	AENOR 0099	2025-08-04	MASCARILLA / MASK

Fecha de emisión / First issued on 2020-09-16
Fecha de modificación / Modified on 2020-11-17
Fecha de expiración / Validity date 2023-09-16

Original Electronic Certificate

AENOR INTERNACIONAL S.A.U.
Génova, 6. 28004 Madrid. España
Tel. 91 432 60 00.- www.aenor.com

Organismo de control acreditado por ENAC con acreditación Nº 1/C-PR354
Control body accredited by ENAC. Accreditation number 1/C-PR354

EU DECLARATION OF CONFORMITY

We Manufacturer: Qingdao Orphila Medical Technology Co., Limited

Address: Rm0501, Futai Square No.18 Hongkong Middle Road, Qingdao, Shandong, China, 266000

Declare that the product detailed below:

Particle Filtering Half Mask

Model: OM-P2195

Batch No.: 202007001a

Satisfies the requirement of the Council Directives:

2016/425/EU

Essential health and safety requirements Guaranteed
and conforms with the norms: EN 149: 2001+A1: 2009

Module B

NOTIFIED BODY: AENOR INTERNACIONAL

NUMBER: 0099

EU TYPE EXAMINATION CERTIFICATE ISSUED: 2020-06-22

Manufacturing plant surveillance through Module D:

NOTIFIED BODY: AENOR INTERNACIONAL

NUMBER: 0099

CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS CERTIFICATE ISSUED: 2020-09-16

Signed for and on behalf of: Qingdao Orphila Medical Technology Co., Limited

Place and date of issue: Rm0501, Futai Square No.18 Hongkong Middle Road, Qingdao, Shandong, China, 266000. Aug. 10th, 2020

Name: Ma fangda

Function: General manager

Signature: Ma fangda

Products

TÜVRheinland®
Precisely Right.

Test Report No.: 178139762a 001

Client: **Qingdao Orphila Medical Technology Co., Limited**
Rm0501, Futai Square No.18 Hongkong middle road, Qingdao, Shandong, China

Contact Person: Rocky Ma

Sample Description As Declared :

No. Of Sample	:	90 Pcs
Product Description	:	OM-KN95-FFP2
Lot No./Batch code	:	202004
Sales Destination(country)	:	Not Provided
Test type	:	Partial test
Product type	:	Single shift use only
Claimed Classification	:	FFP2 NR
Manufacturer Name	:	Qingdao Orphila Medical Technology Co., Limited
Manufacturer Address	:	Plant 20, No. 252 Weihe Road, Huangdao District, Qingdao, Shandong, China

Sample obtaining method: Sending by customer

Sample Receiving date: 2020-04-30
Delivery condition: *Apparent good, Samples tested as received*
Test Period: 2020-05-07 to 2020-06-02

Test specification:	***Test result:***
Particulate respirator-half facepiece EN 149:2001 + A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking^	Please refer to result page

For and on behalf of

TÜV Rheinland / CCIC (Qingdao) Co., Ltd.

2020-06-03 Alex Zhou / Senior Manager

Date *Name/Position*

Test result is drawn according to the kind and extent of tests performed.
This test report relates to the a. m. test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any safety mark on this or similar products.

Material list

Material	Color	Location
Textile	White	White folding mask

Note:

	Shading shows the clauses requested
NRq	The clauses were not requested.
Pass	Requirement satisfied.
Ltd	Testing requested was insufficient completely to verify compliance with the clause. Refer to the "result details section for more information.
Fail	Requirement not satisfied. Refer to the "result details section for more information.
NAs	Assessment not carried out.
NAp	Requirement not applicable.
NT	Requested but not tested due to early termination following failure.

Result:

EN 149:2001+A1:2009 Respiratory protective devices—Filtering half masks to protect against particles—Requirement, testing, marking.

7.4 **Package^** **NRq**

Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.

7.5 **Material^** **PASS [1]**

Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used.

After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.

When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.

Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.

Note 1: In accordance with the requirement.
Specimens -10,-40,-27 were conditioned in accordance with 8.3.1, None of the specimens conditioned suffered mechanical failure or collapse.
Specimens -60,-21,-58 were conditioned in accordance with 8.3.2, None of the specimens conditioned suffered collapse.

7.6 **Cleaning and disinfecting^** **NAp [2]**

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.

Note 2: Single shift use only.

7.7 **Practical performance^** **PASS** [3]

The particle filtering half mask shall undergo practical performance tests under realistic conditions

Note 3: No imperfections.

Specimen and subject details:

Specimen	Subject
-26	LCF
-69	SM

7.8 **Finish of parts^**

Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs. **PASS** [4]

Note 4: None of the specimens used in limited laboratory testing undertaken showed the evidence of sharp edges or burrs.

7.9.1 **Total inward leakage^** **PASS**[5]

For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than: 25% for FFP1, 11% for FFP2, 5% for FFP3;

And, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than: 22% for FFP1, 8% for FFP2, 2% for FFP3.

Note 5: 47 out of the 50 individual exercise results were not greater than 11%; 8 out of the 10 individual wearer arithmetic means were not greater than 8%. Detailed data are showed below.

Table 7.9.1-A Inward leakage test data

Test specification: EN149-2001 Clause 8.5

Subject	Sample No.	Condition	Walk(%)	Head Side/side(%)	Head Up/down(%)	Talk(%)	Walk(%)	Mean(%)
ZMM	-14	A.R.	2.7	8.1	14.0	10.4	5.7	8.2
YZF	-28	A.R.	5.4	7.8	5.1	10.7	3.6	6.5
LCF	-06	A.R.	4.9	6.9	8.9	8.4	5.9	7.0
NXL	-56	A.R.	4.5	6.2	8.7	4.6	5.9	6.0
SM	-16	A.R.	5.1	7.0	9.8	6.6	5.2	6.7
LZM	-37	T.C.	7.5	10.8	12.7	10.3	7.9	9.8
JLX	-07	T.C.	2.8	9.7	9.5	3.7	2.8	5.7
TS	-46	T.C.	4.0	6.9	10.1	5.2	4.0	6.0
ZH	-18	T.C.	1.5	7.9	8.8	6.5	3.5	5.7
TLX	-31	T.C.	6.3	8.7	15.5	2.6	4.8	7.6
Maximum permitted			**11**					**8**

Table 7.9.1-B Facial dimension

Subject	Face length(mm)	Face width(mm)	Face Depth(mm)	Mouth Width(mm)
ZMM	114	157	119	50
YZF	113	151	106	48
LCF	119	165	121	56
NXL	113	147	108	53
SM	116	144	109	49
LZM	118	157	124	44
JLX	119	152	109	59
TS	97	146	102	51
ZH	102	152	113	55
TLX	104	153	112	40

7.9.2 **Penetration of filter material^** **PASS**

The penetration of the filter of the particle filtering half mask shall meet the requirements:

Classification	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
FFP 1	⩽ 20%	⩽ 20%
FFP 2	⩽ 6%	⩽ 6%
FFP 3	⩽ 1%	⩽ 1%

Table 7.9.2- Penetration of filter material

Test specification: EN149-2001 Clause 8.11

Aerosol	Condition	Sample No.	Penetration (%)		Assessment
			After 3 minutes	Max. during exposure	
Sodium chloride test	A.R.	-15	0.43		**PASS**
		-70	2.10		
		-48	0.47		
	S.W.	-55	0.62		
		-24	0.43		
		-57	1.16		
	M.S. + T.C.	-71	0.48	0.49	
		-39	1.30	1.30	
		-74	1.24	1.24	
Paraffin oil test	A.R.	-23	1.22		
		-63	0.57		
		-47	1.30		
	S.W.	-59	0.77		
		-29	0.83		
		-61	0.94		
	M.S. + T.C.	-49	1.18	1.73	
		-67	0.91	1.35	
		-38	1.27	2.08	
Maximum permitted		**6**			
Flow conditioning: Single filter: 95.0 L/min					

7.10 **Compatibility with skin^** **PASS [6]**

Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.

Note 6: Specimens -04, -51, -64, -35, -75(A.R.) and specimens -20, -53, -05, -73, -42(T.C.) were tested. No irritation or any other adverse effect to health.

7.11 **Flammability^** **PASS**

When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5 s after removal from the flame.

Table 7.11- Flammability

Test specification: EN149-2001 Clause 8.6

Condition	Sample No.	Result	Assessment
A.R.	-34	Burn for 0.8 s	PASS
	-11	Burn for 0.7 s	
T.C.	-43	Burn for 0.4 s	
	-41	Burn for 0.5 s	

7.12 **Carbon dioxide content of the inhalation air^** **PASS**

The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume).

Table 7.12- Carbon dioxide content of the inhalation air

Test specification: EN149-2001 Clause 8.7

Condition	Sample No.	Result	Assessment
A.R.	-17	0.34%	PASS
	-52	0.34%	
	-65	0.36%	
Maximum permitted		1.0%	

7.13 **Head harness^** **PASS [7]**

The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.

The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the particle filtering half mask firmly in position and be capable of maintaining total inward leakage requirements for the device.

Note 7: Specimens -45, -32, -08, -68, -66(A.R.) and specimens -12, -44, -36, -54, -22 (T.C.) were tested. Head harness can be donned and removed easily, adjustable or self-adjusting and have sufficiently robust to hold the face mask firmly. The product satisfied the total inward leakage requirements. See 7.9.1 for results.

7.14 **Field of vision^** **PASS [8]**

The field of vision is acceptable if determined so in practical performance tests.

Note 8: Specimens -09 and -25(A.R.) were tested. Pass the practical performance tests and no adverse comments.

7.15 **Exhalation valve^** **NAp**

A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.

If an exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device that may be necessary for the particle filtering half mask to comply with 7.9.

Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.

When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s.

7.16 **Breathing resistance^** **PASS [9]**

Classification	Maximum permitted resistance (mbar)		
	inhalation		exhalation
	30 l/min	95 l/min	160 l/min or (25 cycles/min x 2.0 l/stroke)
FFP1	0,6	2,1	3,0
FFP2	0,7	2,4	3,0
FFP3	1,0	3,0	3,0

Note 9: FFP2 Filtering face mask. Test results are detailed below.

Table 7.16 Breathing resistance (mbar)

Test specification: EN149-2001 Clause 8.9

Specimen	Condition	Inhalation resistance(mbar)		Exhalation resistance(mbar)				
		At 30 l/min	At 95 l/min	Breathing machine(25 cycles/min x 2.0 l/stroke)				
				A	B	C	D	E
-03	A.R.	0.24	0.95	2.12	2.08	2.04	2.03	2.09
-13		0.27	1.04	2.37	2.29	2.31	2.34	2.35
-62		0.24	0.93	2.09	2.07	2.01	2.04	2.05
-72	T.C.	0.24	0.92	2.06	2.12	2.09	2.06	2.09
-19		0.25	0.97	2.11	2.08	2.04	2.03	2.07
-50		0.23	0.91	2.01	2.07	2.05	1.98	2.06
-33	S.W.	0.28	1.07	2.34	2.39	2.33	2.31	2.35
-76		0.25	0.95	2.12	2.16	2.11	2.09	2.14
-30		0.27	1.01	2.28	2.24	2.21	2.29	2.26
	A.R. + F.C.							
	T.C. + F.C.							
Maximum permitted		0.7	2.4	3.0				

A: facing directly ahead; B: facing vertically upwards; C: facing vertically downwards; D: lying on the left side; E: lying on the right side.

7.17 **Clogging^** **NRq [10]**

7.17.2 **Breathing resistance**

Valved particle filtering half masks:
After clogging, the inhalation resistances shall not exceed,
FFP1: 4 mbar, FFP2: 5 mbar, FFP3: 7 mbar at 95 l/min continuous flow;
The exhalation resistance shall not exceed 3 mbar at 160 l/min continuous flow.

Valveless particle filtering half masks:
After clogging the inhalation and exhalation resistances shall not exceed:
FFP1: 3 mbar, FFP2: 4 mbar, FFP3: 5 mbar at 95 l/min continuous flow.

7.17.3 **Penetration of filter material**

Classification	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
FFP 1	⩽ 20%	⩽ 20%
FFP 2	⩽ 6%	⩽ 6%
FFP 3	⩽ 1%	⩽ 1%

Note 10: Single shift use only.

7.18 **Demountable parts^** **NAp [11]**

All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.

Note 11: No demountable parts were used.

9 **Marking^** **NRq**

9.1 **Packaging**

The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.

9.1.1 The name, trademark or other means of identification of the manufacturer or supplier.

9.1.2 Type-identifying marking.

9.1.3 Classification

The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D.

9.1.4 The number and year of publication of this European Standard.

9.1.5 At least the year of end of shelf life. The end of shelf life may be informed by a pictogram as shown in Figure 12a, where yyyy/mm indicates the year and month.

9.1.6 The sentence 'see information supplied by the manufacturer', at least in the official language(s) of the country of destination, or by using the pictogram as shown in Figure 12b.

9.1.7 The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram, as shown in Figures 12c and 12d.

9.1.8 The packaging of those particle filtering half masks passing the dolomite clogging test shall be additionally marked with the letter "D". ID This letter shall follow the classification marking preceded by a single space.

9.2 **Particle filtering half mask^**

Particle filtering half masks complying with this European Standard shall be clearly and durably marked with the following:

9.2.1 The name, trademark or other means of identification of the manufacturer or supplier.

9.2.2 Type-identifying marking.

9.2.3 The number and year of publication of this European Standard.

9.2.4 Classification

The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D.

9.2.5 If appropriate the letter D (dolomite) in accordance with clogging performance. This letter shall follow the classification marking preceded by a single space(see 9.2.4).

Examples FFP3 NR D, FFP2 R D

9.2.6 Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.

10 Information to be supplied by the manufacturer^ **NRq**

10.1 Information supplied by the manufacturer shall accompany every smallest commercial available package.

10.2 Information supplied by the manufacturer shall be at least in the official language(s) of the country of destination.

10.3 The information supplied by the manufacturer shall contain all information necessary for trained and qualified persons on

application/limitations; the meaning of any colour coding; checks prior to use; donning fitting; use; maintenance(e.g. cleaning, disinfecting), if applicable; storage; the meaning of any symbols/pictograms used of the equipment.

10.4 The information shall be clear and comprehensible. If helpful, illustrations, part numbers, marking shall be added.

10.5 Warning shall be given against problems likely to be encountered, for example:

- fit of particle filtering half mask (check prior to use);
- it is unlikely that the requirements for leakage will be achieved if facial hair passes under the face seal;
- air quality (contaminants, oxygen deficiency);
- use of equipment in explosive atmosphere.

10.6 The information shall provide recommendations as to when the particle filtering half mask shall be discarded.

10.7 For devices marked "NR", a warning shall be given that the particle filtering half mask shall not be used for more than one shift.

Remark: "^" indicates that the test is sub-contracted to the lab China Academy of Safey Science and Technology which complies with the requirement of ISO/IEC 17025:2017, the registration No. CNAS L0118.

Photo:

- END -

General Terms and Conditions of Business of TÜV Rheinland in Greater China

1. Scope

1.1 These General Terms and Conditions of Business of TÜV Rheinland in Greater China ("GTCB") is made between the client and one or more member entities of TÜV Rheinland in Greater China as applicable as the case may be ("TÜV Rheinland"). The Greater China hereof refers to Mainland China, Hong Kong and Taiwan. The client hereof includes:

(i) a natural person capable to form legally binding contracts under the applicable laws who concludes the contract not for the purpose of a daily use;

(ii) the incorporated or unincorporated entity duly organized, validly existing and capable to form legally binding contracts under the applicable law.

1.2 The following terms and conditions apply to agreed services including consultancy services, information, deliveries and similar services as well as ancillary services and other secondary obligations provided within the scope of contract performance.

1.3 Any standard terms and conditions of the client of any nature shall not apply and shall hereby be expressly excluded. No standard contractual terms and conditions of the client shall form part of the contract even if TÜV Rheinland does not explicitly object to them.

1.4 In the context of an ongoing business relationship with the client, this GTCB shall also apply to future contracts with the client without TÜV Rheinland having to refer to them separately in each individual case.

2. Quotations

Unless otherwise agreed, all quotations submitted by TÜV Rheinland can be changed by TÜV Rheinland without notice prior to its acceptance and confirmation by the other party.

3. Coming into effect and duration of contracts

3.1 The contract shall come into effect for the agreed terms upon the quotation letter of TÜV Rheinland or a separate contractual document being signed by both contracting parties, or upon the works requested by the client being carried out by TÜV Rheinland. If the client instructs TÜV Rheinland without receiving a quotation from TÜV Rheinland (quotation), TÜV Rheinland is, in its sole discretion, entitled to accept the order by giving written notice of such acceptance (including notice sent via electronic means) or by performing the requested services.

3.2 The contract term starts upon the coming into effect of the contract in accordance with article 3.1 and shall continue for the term agreed in the contract.

3.3 If the contract provides for an extension of the contract term, the contract term will be extended by the term provided for in the contract unless terminated in writing by either party with a six-week notice prior to the end of the contractual term.

4. Scope of services

4.1 The scope and type of the services to be provided by TÜV Rheinland shall be specified in the contractually agreed service scope of TÜV Rheinland by both parties. If no such separate service scope of TÜV Rheinland exists, then the written confirmation of order by TÜV Rheinland shall be decisive for the service to be provided.

4.2 The agreed services shall be performed in compliance with the regulations in force at the time the contract is entered into.

4.3 TÜV Rheinland is entitled to determine, in its sole discretion, the method and nature of the assessment unless otherwise agreed in writing or if mandatory provisions require a specific procedure to be followed.

4.4 On execution of the work there shall be no simultaneous assumption of any guarantee of the correctness (proper quality) and working order of either tested or examined parts nor of the installation as a whole and its upstream and/or downstream processes, organisations, use and application in accordance with regulations, nor of the systems on which the installation is based. In particular, TÜV Rheinland shall assume no responsibility for the construction, selection of materials and assembly of installations examined, nor for their use and application in accordance with regulations, unless these questions are expressly covered by the contract.

4.5 In the case of inspection work, TÜV Rheinland shall not be responsible for the accuracy or checking of the safety programmes or safety regulations on which the inspections are based, unless otherwise expressly agreed in writing.

4.6 If mandatory legal regulations and standards or official requirements for the agreed service scope change after conclusion of the contract, with a written notice to the client, TÜV Rheinland shall be entitled to additional remuneration for resulting additional expenses.

4.7 The services to be provided by TÜV Rheinland under the contract are agreed exclusively with the client. A contract of third parties with the services of TÜV Rheinland, as well as making available of and justifying confidence in the work results (test reports, test results, expert reports, etc.) is not part of the agreed services. This also applies if the client passes on work results - in full or in extracts - to third parties in accordance with clause 11.4.

5. Performance periods/dates

5.1 The contractually agreed periods/dates of performance are based on estimates of the work involved which are prepared in line with the details provided by the client. They shall only be binding if being confirmed as binding by TÜV Rheinland in writing.

5.2 If binding periods of performance have been agreed, these periods shall not commence until the client has submitted all required documents to TÜV Rheinland.

5.3 Articles 5.1 and 5.2 also apply, even without express approval by the client, to all extensions of agreed periods/dates of performance not caused by TÜV Rheinland.

5.4 TÜV Rheinland is not responsible for a delay in performance, in particular if the client has not fulfilled his duties to cooperate in accordance with clause 6.1 or has not done so in time and, in particular, has not provided TÜV Rheinland with all documents and information required for the performance of the service as specified in the contract.

5.5 If the performance of TÜV Rheinland is delayed due to unforeseeable circumstances such as force majeure, strikes, business disruptions, governmental regulations, transport obstacles, etc., TÜV Rheinland is entitled to postpone performance for a reasonable period of time which corresponds at least to the duration of the hindrance plus any time period which may be required to resume performance.

6. The client's obligation to cooperate

6.1 The client shall guarantee that all cooperation required on its part, its agents or third parties will be provided in good time and at no cost to TÜV Rheinland.

6.2 Design documents, supplies, auxiliary staff, etc. necessary for performance of the services shall be made available free of charge by the client. Moreover, collaborative action of the client must be undertaken in accordance with legal provisions, standards, safety regulations and accident prevention instructions. And the client represents and warrants that:

a) it has required statutory qualifications;

b) the product, service or management system to be certified complies with applicable laws and regulations; and

c) it doesn't have any illegal and dishonest behaviours or is not included in the list of Enterprises with Serious Illegal and Dishonest Acts of People's Republic of China.

If the client breaches the aforesaid representations and warranties, TÜV Rheinland is entitled to i) immediately terminate the contract/order without prior notice; and ii) withdraw the issued testing report/certificates if any.

6.3 The client shall bear any additional cost incurred on account of work having to be redone or being delayed as a result of late, incorrect or incomplete information provided by or lack of proper cooperation from the client. Even where a fixed or maximum price is agreed, TÜV Rheinland shall be entitled to charge extra fees for such additional expense.

7. Prices

7.1 If the scope of performance is not laid down in writing when the order is placed, invoicing shall be based on costs actually incurred. If no price is agreed in writing, invoicing shall be made in accordance with the price list of TÜV Rheinland valid at the time of performance.

7.2 Unless otherwise agreed, work shall be invoiced according to the progress of the work.

7.3 If the execution of an order extends over more than one month and the value of the contract or the agreed fixed price exceeds €2,500.00 or equivalent value in local currency, TÜV Rheinland may demand payments on account or in instalments.

8. Payment terms

8.1 All invoice amounts shall be due for payment without deduction on receipt of the invoice. No discounts and rebates shall be granted.

8.2 Payments shall be made to the bank account of TÜV Rheinland as indicated on the invoice, stating the invoice and client numbers.

8.3 In cases of default of payment, TÜV Rheinland shall be entitled to claim default interest at the applicable short term loan interest rate publicly announced by a reputable commercial bank in the country where TÜV Rheinland is located. At the same time, TÜV Rheinland reserves the right to claim further damages.

8.4 Should the client default in payment of the invoice despite being granted a reasonable grace period, TÜV Rheinland shall be entitled to cancel the contract, withdraw the certificate, claim damages for non-performance and refuse to continue performance of the contract.

8.5 The provisions set forth in article 8.4 shall also apply in cases involving returned cheques, cessation of payment, commencement of insolvency proceedings against the client's assets or cases in which the commencement of insolvency proceedings has been dismissed due to lack of assets.

8.6 Objections to the invoices of TÜV Rheinland shall be submitted in writing within two weeks of receipt of the invoice.

8.7 TÜV Rheinland shall be entitled to demand appropriate advance payments.

8.8 TÜV Rheinland shall be entitled to raise its fees at the beginning of a month if overheads and/or purchase costs have increased. In this case, TÜV Rheinland shall notify the client in writing of the rise in fees. This notification shall be issued one month prior to the date on which the rise in fees shall come into effect (period of notice of changes in fees). If the rise in fees remains under 5% per contractual year, the client shall not have the right to terminate the contract. If the rise in fees exceeds 5% per contractual year, the client shall be entitled to terminate the contract by the end of the period of notice of changes in fees. If the contract is not terminated, the changed fees shall be deemed to have been agreed upon by the time of the expiry of the notice period.

8.9 Only legally established and undisputed claims may be offset against claims by TÜV Rheinland.

9. Acceptance of work

9.1 Any part of the work result ordered which is complete in itself may be presented by TÜV Rheinland for acceptance as an instalment. The client shall be obliged to accept it immediately.

9.2 If acceptance is required or contractually agreed in an individual case, this shall be deemed to have taken place two (2) weeks after completion and handover of the work, unless the client refuses acceptance within this period stating at least one fundmental breach of contract by TÜV Rheinland.

9.3 The client is not entitled to refuse acceptance due to insignificant breach of contract by TÜV Rheinland.

9.4 If acceptance is excluded according to the nature of the work performance of TÜV Rheinland, the completion of the work shall take its place.

9.5 If the client was unable to make use of the time windows provided for within the scope of a certification procedure for auditing/performance by TÜV Rheinland and the certificate is therefore to be withdrawn (e.g. performance of surveillance audits), TÜV Rheinland is entitled to immediately charge a lump-sum compensation of 10% of the order amount as compensation for expenses. The client reserves the right to prove that the TÜV Rheinland has incurred no damage whatsoever or only a considerably lower damage than the above lump sum.

9.6 Insofar as the client has undertaken in the contract to accept services, TÜV Rheinland shall also be entitled to charge lump-sum damages in the amount of 10% of the order amount as compensation for expenses if the service is not called within one year after the order has been placed. The client reserves the right to prove that the TÜV Rheinland has incurred no damage whatsoever or only a considerably lower damage than the above mentioned lump sum.

10. Confidentiality

10.1 For the purpose of these terms and conditions, "confidential information" means all information, documents, images, drawings, know-how, data, samples and project documentation which one party (the "disclosing party") hands over, transfers or otherwise discloses to the other party (the "receiving party"), and the confidential information created during performance of work by TÜV Rheinland, including product testing data, defects, conformity to the technical standard and related reports. Confidential information also includes paper copies and electronic copies of such information. Confidential information is expressly not the data and know-how collected, compiled or otherwise obtained by TÜV Rheinland (non-personal) within the scope of the provision of services by TÜV Rheinland. TÜV Rheinland is entitled to store, use, further develop and pass on the data obtained in connection with the provision of services for the purposes of developing new services, improving services and analysing the provision of services.

10.2 The disclosing party shall mark all confidential information disclosed in written form as confidential before passing it onto the receiving party. The same applies to confidential information transmitted by e-mail. If confidential information is disclosed orally, the receiving party shall be appropriately informed in advance and the disclosing party shall confirm in writing the confidentiality nature of the information within five working days of oral disclosure. Where the disclosing party fails to do so within the stipulated period, the receiving party shall not take any confidentiality obligations hereunder towards such information.

10.3 All confidential information which the disclosing party transmits or otherwise discloses to the receiving party and which is created during performance of work by TÜV Rheinland:

a) may only be used by the receiving party for the purposes of performing the contract, unless expressly otherwise agreed in writing by the disclosing party;

b) may not be copied, distributed, published or otherwise disclosed by the receiving party, unless this is necessary for fulfilling the purpose of the contract or TÜV Rheinland is required to pass on confidential information, inspection reports or documentation to the government authorities, judicial court, accreditation bodies or third parties that are involved in the performance of the contract;

c) must be treated by the receiving party with the same level of confidentiality as the receiving party uses to protect its own confidential information, but never with a lesser level of confidentiality than that which is reasonably required.

10.4 The receiving party may disclose any confidential information received from the disclosing party only to those of its employees who need this information to perform the services required for the contract. The receiving party undertakes to oblige these employees to observe the same level of secrecy as set forth in this confidentiality clause.

10.5 Information for which the receiving party can furnish proof that:

a) it was generally known at the time of disclosure or has become general knowledge without violation of this confidentiality clause by the receiving party; or

b) it was disclosed to the receiving party by a third party entitled to disclose this information; or

c) the receiving party already possessed this information prior to disclosure by the disclosing party; or

d) the receiving party developed it itself, irrespective of disclosure by the disclosing party, shall not be deemed to constitute "confidential information" as defined in this confidentiality clause.

10.6 All confidential information shall remain the property of the disclosing party. The receiving party hereby agrees to immediately (i) return all confidential information, including all copies, to the disclosing party, and/or (ii) on request by the disclosing party, to destroy all confidential information, including all copies, and confirm the destruction of this confidential information to the disclosing party in writing, at any time if so requested by the disclosing party but at the latest and without special request after termination or expiry of the contract. This does not extend to include reports and certificates prepared for the client solely for the purpose of fulfilling the obligations under the contract, which shall remain with the client. However, TÜV Rheinland is entitled to make file copies of such reports, certificates and confidential information that forms the basis for preparing these reports and certificates in order to evidence the correctness of its results and for general documentation purposes required by laws, regulations and the requirements of working procedures of TÜV Rheinland.

10.7 From the start of the contract and for a period of three years after termination or expiry of the contract, the receiving party shall maintain strict secrecy of all confidential information and shall not disclose this information to any third parties or use it for itself.

11. Copyrights and rights of use, publications

11.1 TÜV Rheinland shall retain all exclusive copyrights in the reports, expert reports/opinions, test reports/results, results, calculations, presentations etc. prepared by TÜV Rheinland, unless otherwise agreed by the parties in a separate agreement. As the owner of the copyrights, TÜV Rheinland is free to grant others the right to use the work results for individual or all types of use ("right of use")

11.2 The client receives a simple, unlimited, non-transferable, non-sublicensable right of use to the contents of the work results produced within the scope of the contract, unless otherwise agreed by the parties in a separate agreement.The client may only use such reports, expert reports/opinions, test reports/results, results calculations, presentations etc. prepared within the scope of the contract for the contractually agreed purpose.

11.3 The transfer of right of use of the generated work results regulated in clause 11.2. of the GTCB is subject to full payment of the remuneration agreed in favour of TÜV Rheinland.

11.4 The client may use work results only complete and unshortened. The client may only pass on the work results in full unless TÜV Rheinland has given its prior written consent to the partial passing on of work results.

11.5 Any publication or duplication of the work results for advertising purposes or any further use of the work results beyond the scope regulaed in clause 11.2 needs the prior written approval of TÜV Rheinland in each individual case.

11.6 TÜV Rheinland may revoke a once given approval according to clause 11.5 at any time without stating reasons. In this case, the client is obliged to stop the transfer of the work results immediately at his own expense and, as far as possible, to withdraw publications.

11.7 The consent of TÜV Rheinland to publication or duplication of the work results does not entitle the client to use the corporate logo, corporate design or test/certification mark of TÜV Rheinland.

12. Liability of TÜV Rheinland

12.1 Irrespective of the legal basis, to the fullest extent permitted by applicable law, in the event of a breach of contractual obligations or tort, the liablity of TÜV Rheinland for all damages, losses and reimbursement of expenses caused by TÜV Rheinland, its legal representatives and/or employees shall be limited to: (i) in the case of a contract with a fixed overall fee, three times the overall fee for the entire contract; (ii) in the case of a contract for annually recurring services, the agreed annual fee; (iii) in the case of a contract expressly charged on a time and material basis, a maximum of 20,000 Euro or equivalent amount in local currency; and (iv) in the case of a framework agreement that provides for the possibility of placing individual orders, three times of the fee for the individual order under which the damages or losses have occurred. Notwithstanding the above, in the event that the total and accumulated liability calculated according to the foregoing provisions exceeds 2.5 Million Euro or equivalent amount in local currency, the total and accumulated liability of TÜV Rheinland shall be only limited to and shall not exceed the said 2.5 Million Euro or equivalent amount in local currency.

12.2 The limitation of liability according to article 12.1 above shall not apply to damages and/or losses caused by malice, intent or gross negligence on the part of TÜV Rheinland or its vicarious agents. Such limitation shall not apply to damages for a person's death, physical injury or illness.

12.3 In cases involving a fundamental breach of contract, TÜV Rheinland will be liable even where minor negligence is involved. For this purpose, a "fundamental breach" is breach of a material contractual obligation, the performance of which permits the due performance of the contract. Any claim for damages for a fundamental breach of contract shall be limited to the amount of damages reasonably foreseen as a possible consequence of such breach of contract at the time of the breach (reasonably foreseeable damages), unless any of the circumstances described in article 12.2 applies.

12.4 TÜV Rheinland shall not be liable for the acts of the personnel made available by the client to support TÜV Rheinland in the performance of its services under the contract, unless such personnel made available is regarded as vicarious agent of TÜV Rheinland. If TÜV Rheinland is not liable for the acts of the personnel made available by the client under the foregoing provision, the client shall indemnify TÜV Rheinland against any claims made by third parties arising from or in connection with such personnel's acts.

12.5 Unless otherwise contractually agreed in writing, TÜV Rheinland shall only be liable under the contract to the client.

12.6 The limitation periods for claims for damages shall be based on statutory provisions.

12.7 None of the provisions of this article 12 changes the burden of proof to the disadvantage of the client.

13. Export control

13.1 When passing on the services provided by TÜV Rheinland or parts thereof to third parties in Greater China or other regions, the client must comply with the respectively applicable regulations of national and international export control law.

13.2 The performance of a contract with the client is subject to the proviso that there are no obstacles to performance due to national or international foreign trade legislations or embargos and/or sanctions. In the event of a violation, TÜV Rheinland shall be entitled to terminate the contract with immediate effect and the client shall compensate for the losses incured thereof by TÜV Rheinland.

14. Data protection notice

TÜV Rheinland processes personal data of the client for the purpose of fulfilling this contract. In addition, TÜV Rheinland also processes the data for other legal purposes in accordance with the relevant legal basis. The personal data of the client will only be disclosed to other natural or legal persons if the legal requirements are met. This also applies to transfers to third countries. The personal data will be deleted immediately as soon as a corresponding reason for deletion arises. Data subjects may exercise the following rights: right of information, right of rectification, right of deletion, right of processing limitation, right of objection, right of data transferability. In addition, persons concerned by the data processing have the right to revoke their consent at any time with effect for the future, as well as the right to file a complaint with the competent data protection supervisory authority. For further details on the processing of personal data by TÜV Rheinland as the person responsible or contract processor, please refer to the respective data protection information. You can contact the Group Data Protection Officer of TÜV Rheinland by e-mail at datenschutz@de.tuv.com or by post at the following address: TÜV Rheinland AG, c/o Group Data Protection Officer, Am Grauen Stein, 51105 Cologne, Germany.

15. Test material: transport risk and storage

15.1 The risk and costs for freight and transport of documents or test material to and from TÜV Rheinland as well as the costs of necessary disposal measures shall be borne by the client.

15.2 Any destroyed and otherwise worthless test material will be disposed of by TÜV Rheinland for the client at the expense of the client, unless otherwise agreed.

15.3 Undamaged test material shall be stored by TÜV Rheinland for four (4) weeks after completion of the test. If a longer storage period is desired, TÜV Rheinland charges an appropriate storage fee.

15.4 After the expiry of the 4 weeks or any longer period agreed upon, the test material will be disposed of by TÜV Rheinland for the client for a fee in accordance with clause 15.2.

16. Termination of the contract

16.1 Notwithstanding clause 3.3 of the GTCB, TÜV Rheinland and the client are entitled to terminate the contract in its entirety or, in the case of services combined in one contract, each of the combined parts of the contract individually and independently of the continuation of the remaining services with six (6) months' notice to the end of the contractually agreed term.

16.2 For good causes, TÜV Rheinland may consider giving a written notice to the client to terminate the contract which includes but not limited to the following:

a) the client does not immediately notify TÜV Rheinland of changes in the conditions within the company which are relevant for certification or signs of such changes;

b) the client misuses the certificate or certification mark or uses it in violation of the contract;

c) in the event of several consecutive delays in payment (at least three times);

d) a substantial deterioration of the financial circumstances of the client occurs and as a result the payment claims of TÜV Rheinland under the contract are considerably endangered and TÜV Rheinland cannot reasonably be expected to continue the contractual relationship.

16.3 In the event of termination with written notice by TÜV Rheinland for good cause, TÜV Rheinland shall be entitled to a lump-sum claim for damages against the client if the conditions of a claim for damages exist. In this case, the client shall owe 15% of the remuneration to be paid until the end of the fixed contract term as lump-sum compensation. The client reserves the right to prove that there is no damage or a considerably lower damage, TÜV Rheinland reserves the right to prove a considerably higher damage in individual cases.

16.4 TÜV Rheinland is also entitled to terminate the contract with written notice if the client has not been able to make use of the time windows for auditing /service provision provided by TÜV Rheinland within the scope of a certification procedure and the certificate therefore has to be withdrawn (for example during the performance of monitoring audits). Clause 16.3 applies accordingly.

17. Partial invalidity, written form, place of jurisdiction and dispute resolution

17.1 All amendments and supplements must be in writing in order to be effective. This also applies to amendments and supplements to this clause 17.1.

17.2 Should one or several of the provisions under the contract and/or these terms and conditions be or become ineffective, the contracting parties shall replace the invalid provision with a legally valid provision that comes closest to the content of the invalid provision in legal and commercial terms.

17.3 Unless otherwise stipulated in the contract, the governing law of the contract and these terms and conditions shall be chosen following the rules as below:

a) if TÜV Rheinland in question is legally registered and existing in the People's Republic of China, the contracting parties hereby agree that the contract and these terms and conditions shall be governed by the laws of the People's Republic of China.

b) if TÜV Rheinland in question is legally registered and existing in Taiwan, the contracting parties hereby agree that the contract and these terms and conditions shall be governed by the laws of Taiwan.

c) if TÜV Rheinland in question is legally registered and existing in Hong Kong, the contracting parties hereby agree that the contract and these terms and conditions shall be governed by the laws of Hong Kong.

17.4 Any dispute in connection with the contract and these terms and conditions or the execution thereof shall be settled friendly through negotiations.

Unless otherwise stipulated in the contract, if no settlement or no agreement in respect of the extension of the negotiation period can be reached within two months of the arising of the dispute, the dispute shall be submitted:

a) in the case of TÜV Rheinland in question being legally registered and existing in the People's Republic of China, to China International Economic and Trade Arbitration Commission (CIETAC) to be settled by arbitration under the Arbitration Rules of CIETAC in force when the arbitration is submitted. The arbitration shall take place in Beijing, Shanghai, Shenzhen or Chongqing as appropriately chosen by the claiming party.

b) in the case of TÜV Rheinland in question being legally registered and existing in Taiwan, to Chinese Arbitration Association Taipei Branch to be arbitrated in accordance with its then current Rules of Arbitration. The arbitration shall take place in Taipei.

c) in the case of TÜV Rheinland being legally registered and existing in Hong Kong, to Hong Kong International Arbitration Centre (HKIAC) to be settled by arbitration under the HKIAC Administered Arbitration Rules in force when the Notice of Arbitration is submitted in accordance with these rules. The arbitration shall take place in Hong Kong.

The decision of the relevant arbitration tribunal shall be final and binding on both parties. The arbitration fee shall be borne by the losing party.

May 2019

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检测
TESTING
CNAS L10118

国检检测
CHINA COMPONENTS TEST

Test Report

（2020） WSZ FHL NO.W0614

Product Name Orphila P2195

Client Qingdao Orphila Medical Technology Co.,Limited

Manufacturer Qingdao Orphila Medical Technology Co.,Limited

Test Type Entrusted inspection

Jiangsu Guojian Testing Technology Co., Ltd.

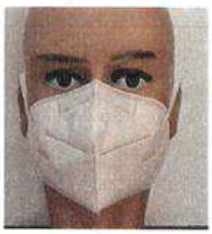
苏国健检测技术有限公司
检验专用章

Test Report

[2020] WSZ FHL NO.W0614

Product name	Orphila P2195	Specification	OM-KP95-P2
		Brand	—
Client/Add/Tel	Qingdao Orphila Medical Technology Co.,Limited / ROOM 501 BUILDNG 1 NO 18. HONG KONG MIDDLE ROAD, SHINAN DISTRICT, QINGDAO SHANDONG, CHINA/—		
Manufacturer/ Add/Tel	Qingdao Orphila Medical Technology Co.,Limited / ROOM 501 BUILDNG 1 NO 18. HONG KONG MIDDLE ROAD, SHINAN DISTRICT, QINGDAO SHANDONG, CHINA/—		
Sample grade	FFP2	Sample number	GWW0614-2020
Sample quantity	110 pcs	Receiving date of sample	14/05/2020
Test type	Entrusted inspection	Article number/Batch number/Style number	—
Test date	14/05/2020~22/05/2020	Testing sites	Testing room
Sample state	Meeting the requirements of testing	Sample description	—
Test standard(s)	EN 149:2001+A1:2009 Respiratory protective devices-Filtering half masks to protect against particles- Requirements,testing, marking		
Test items	Visual inspection, practical performance, finish of parts, compatibility with skin, flammability, carbon dioxide content of the inhalation air, material, head harness, field of vision, penetration of filter material, breathing resistance, total inward leakage		
Test conclusion	The sample upon testing, the test items meet the requirements of the EN 149:2001+A1:2009 standard. The detail of test results see on Pages 2-5. Issue date: 27/05/2020		
Note	For the entrusted sample test, the technical responsibilities are undertaken for the test results of the supplied samples only.		

江苏国健检测技术有限公司 检验专用章



Approver: Reviewer: Chief Tester:

Test Report

S.No.	Test item		Unit	Technical requirements	Test result		Single item decision
1	Visual inspection	Packaging	—	Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.	Packaging withstands mechanical damage and contamination.		Qualified
		Material	—	Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used.	Materials withstand handling and wear.		
2	Practical performance	Head harness comfort	—	Head harness should be comfort.	Sample 1 has the feeling of comfortable wearing		Qualified
					Sample 2 has the feeling of comfortable wearing		
		Security of fastenings	—	Fastenings are safe and reliable	Sample 1: All fastenings are firm.		
					Sample 2: All fastenings are firm		
		Field of vision	—	Field of vision is acceptable	Sample 1: Having a wider visual field		
					Sample 2: Having a wider visual field		
3	Finish of parts		—	Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	Parts of the device have no sharp edges and burrs		Qualified
4	Compatibility with skin		—	Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.	A.R.	5 pcs all don't cause irritation	Qualified
					T.C.	5 pcs all don't cause irritation	
5	Flammability		—	When tested,the particle filtering half mask shall not burn or not to continue to burn for more than 5s after removal from the flame.	A.R.	The Sample is burning. Burning time:0.1s	Qualified
						The Sample is burning. Burning time:0.1s	
					T.C.	The Sample is burning. Burning time:0.1s	
						The Sample is burning. Burning time:0.1s	

Test Report

S.No.	Test item		Unit	Technical requirements	Test result				Single item decision
6	Carbon dioxide content of the inhalation air		—	≤1.0% (by volume)	Sample 1	0.6300%			Qualified
					Sample 2	0.6310%			
					Sample 3	0.6320%			
					Average value	0.63%			
7	Material		—	After undergoing S.W., none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.	Sample 1: neither facepiece nor straps have mechanical failure				Qualified
					Sample 2: neither facepiece nor straps have mechanical failure				
					Sample 3: neither facepiece nor straps have mechanical failure				
				After undergoing S.W. and T.C. , none of the particle filtering half masks shall not collapse.	Sample 1: no collapse				
					Sample 2 : no collapse				
					Sample 3: no collapse				
8	Head harness		—	The head harness shall be designed so that the particle filtering half mask can be donned and removed easily The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the particle filtering half mask firmly in position	A.R.	All of 5 pieces particle filtering half mask meet the requirements			Qualified
					T.C.	All of 5 pieces particle filtering half mask meet the requirements			
9	Field of vision		—	The field of vision is acceptable if determined so in practical performance tests.	The two samples both have a wider visual field				Qualified
10	Penetration of filter material	Sodium chloride	—	≤6%	A.R.	0.4%	0.5%	0.5%	Qualified
					S.W.	0.5%	0.6%	0.5%	
					M.S+T.C.	0.8%	0.7%	0.7%	
		Paraffin oil	—	≤6%	A.R.	2.7%	2.6%	2.7%	Qualified
					S.W.	2.5%	2.6%	2.7%	
					M.S+T.C.	5.9%	5.9%	5.9%	

Test Report

S.No.	Test item		Unit	Technical requirements	Test result						Single item decision
					Exercises	Facing directly ahead	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side	
11	Breathing resistance	Inhalation 30 L/min	mbar	≤0.7	A.R.	0.4	0.4	0.5	0.4	0.4	Qualified
						0.4	0.4	0.5	0.4	0.4	
						0.4	0.4	0.5	0.4	0.4	
					S.W.	0.4	0.4	0.4	0.4	0.4	
						0.4	0.4	0.4	0.4	0.5	
						0.5	0.4	0.4	0.4	0.4	
					T.C.	0.4	0.4	0.4	0.5	0.5	
						0.4	0.4	0.5	0.4	0.4	
						0.4	0.4	0.5	0.4	0.4	
		Inhalation 95 L/min		≤2.4	A.R.	1.3	1.3	1.4	1.3	1.3	Qualified
						1.3	1.3	1.3	1.4	1.3	
						1.3	1.3	1.2	1.3	1.3	
					S.W.	1.3	1.3	1.2	1.2	1.3	
						1.3	1.3	1.2	1.3	1.3	
						1.3	1.2	1.3	1.3	1.3	
					T.C.	1.3	1.2	1.2	1.2	1.3	
						1.3	1.3	1.3	1.2	1.2	
						1.2	1.2	1.3	1.3	1.3	
		Exhalation 160 L/min		≤3.0	A.R.	1.8	1.9	1.9	1.9	1.9	Qualified
						1.9	1.9	1.9	1.9	1.9	
						1.9	2.0	1.9	2.0	2.0	
					S.W.	1.9	1.9	1.8	1.8	1.8	
						1.8	1.9	1.9	1.9	1.9	
						1.9	1.9	1.8	1.8	1.8	
					T.C.	1.8	1.8	1.9	1.9	1.9	
						1.9	1.9	1.8	1.8	1.8	
						1.8	1.9	1.9	1.9	1.9	

Test Report

S.No.	Test item	Unit	Technical requirements	Test result								Single item decision
				Exercises		E1 (%)	E2 (%)	E3 (%)	E4 (%)	E5 (%)	TIL (%)	
12	Total inward leakage	—	At least 46 out of the 50 individual exercise results shall be not greater than 11%; And in addition,at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than 8%.	A.R.	1#	6.3	6.7	7.0	6.8	6.3	6.6	Qualified
					2#	6.2	7.0	7.1	7.1	6.4	6.8	
					3#	6.1	7.1	7.4	7.2	6.6	6.9	
					4#	6.2	6.8	6.7	6.9	6.2	6.6	
					5#	6.2	7.0	7.1	7.0	6.3	6.7	
				T.C.	6#	6.6	7.2	7.4	7.1	6.6	7.0	
					7#	6.0	6.4	6.4	6.6	6.0	6.3	
					8#	5.8	6.4	6.8	6.6	6.0	6.3	
					9#	6.3	6.7	6.8	6.9	6.4	6.6	
					10#	6.8	7.4	7.4	7.7	7.0	7.3	
Note												

The end

Products

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Report No.:	178141074a 001

Client:	**QINGDAO ORPHILA MEDICAL TECHNOLOGY CO.,LIMITED**
Contact Information:	Rm0501, Futai Square No.18 Hongkong Middle road, Qingdao, Shangdong, China
Identification/ Model No(s):	OM-KN95-FFP2, OM-P2295, OM-P3299, OM-P31100, OM-CPA-FFP2-1860, OM-CPA-FFP3-8210, OM-P31100A, OM-P2295A, OM-P3299A, OM-P2295B, OM-P3299B, OM-P2295BA, OM-P3299BA, OM-P2295D, OM-P3299D, OM-P2195, OM-P3399A, OM-N99-FFP3, OM-N99D-FFP3
Sample obtaining method:	Sending by customer
Sample Receiving date:	2020-06-09
Testing Period:	2020-06-09 - 2020-06-16

Test Specification:	*Test result:*
1. Total Lead and Cadmium	PASS
2. Organotin compounds content	PASS
3. Polybrominated biphenyls (PBB)	PASS
4. Phthalates content	PASS
5. NP and NPEO content - according to REACH regulation (EC) No. 1907/2006 Annex XVII Entry 46 and 46a and amendments	PASS
6. Perfluorooctanoic acid (PFOA) and its salts	PASS
7. Screening of substances of very high concern (SVHC) subject to authorisation, according to (EU) No 143/2011, (EU) No 125/2012, (EU) No 348/2013 ,(EU) No 895/2014, (EU) No. 2017/999 and (EU) No. 2020/171 (Annex XIV of EC No 1907/2006) and candidate list by European Chemical Agency (ECHA), according to the EU Court of Justice rules on SVHCs in articles (Guidance on requirements for substances in articles, June 2017)	Please refer to page 12 - 13

Other information:

Lot No./ Batch code: 202006
Manufacturer: Qingdao Orphila Medical Technology Co., Limited. West Coast Branch
Address: Plant 20, No.252 Weihe Road, Huangdao District, Qingdao, Shandong, China

For and on behalf of
TÜV Rheinland/CCIC (Qingdao) Co., Ltd.

Alex zhou

2020-06-17 — Alex Zhou / Senior Manager

Date — *Name/Position*

Material List:

Item: OM-KN95-FFP2, OM-P2295, OM-P3299, OM-P31100, OM-CPA-FFP2-1860, OM-CPA-FFP3-8210, OM-P31100A, OM-P2295A, OM-P3299A, OM-P2295B, OM-P3299B, OM-P2295BA, OM-P3299BA, OM-P2295D, OM-P3299D, OM-P2195, OM-P3399A, OM-N99-FFP3, OM-N99D-FFP3

Material No.	Material	Color	Location
A001	Metal	-	Silver metal wire
A002	Plastic	-	White plastic strip
A003	Plastic	-	White plastic breath valve
A004	Plastic	-	Yellow plastic breath valve
A005	Foam	-	White foam
A006	Plastic + Textile	-	White elastic cord
A007	Fabric	-	White outside leak proof non-woven fabric
A008	Fabric	-	White inner non-woven fabric
A009	Fabric	-	White direct contact layer
A010	Fabric	-	White high density filter layer
A011	Fabric	-	White high density filter layer （A）
A012	Fabric	-	White high density filter layer （B）

1.Total Lead and Cadmium

Test Method: Acid digestion, analyzed by ICP-OES

Test result:

Test No.	Material No.	Test Parameter	Unit	RL	Regulatory Requirement	Test Result	Conclusion
T001	A001	Lead	mg/kg	10	500	22	PASS
		Cadmium	mg/kg	10	100	< RL	
T002	A002 + A003 + A004	Lead	mg/kg	10	500	< RL	PASS
		Cadmium	mg/kg	10	100	< RL	
T003	A005 + A006	Lead	mg/kg	10	500	< RL	PASS
		Cadmium	mg/kg	10	100	< RL	
T004	A007 + A008 + A009	Lead	mg/kg	10	500	< RL	PASS
		Cadmium	mg/kg	10	100	< RL	
T005	A010 + A011 + A012	Lead	mg/kg	10	500	< RL	PASS
		Cadmium	mg/kg	10	100	< RL	

Abbreviation: < = less than
RL = Reporting Limit
mg/kg = milligram per kilogram
1% = 10000 mg/kg

Remark:

* Regulations on Cadmium

		Maximum Permissible Limit				
Country	**Legislation**	**Plastic materials**	**Paint (wet state)**	**Paint on the painted articles**	**Paint (high zinc content)**	**Metal parts of jewellery and imitation jewellery articles and hair assessories**
EC	REACH regulation (EC) No. 1907/2006 Annex XVII Entry 23 and its amendments	100mg/kg	100mg/kg	1000mg/kg	1000mg/kg	100mg/kg

		Maximum Permissible Limit
Country	**Legislation**	**Paint, plastic, plating/ coating of surface treatment**
Switzerland	Switzerland Chemikalien-Risikoreduktions-Verordnung-ChemRRV, 814.81, 18 May 2005	100mg/kg

* Regulations on Lead:

		Maximum Permissible Limit
Country	**Legislation**	**Substances or mixtures intended to use as paint**
EU	Paragraph 1-6 of Entry 63 of Annex XVII, REACH Regulation (EC) No. 1907/2006	For Jewellery, imitation jewellery, hair accessories, bracelets, necklaces , rings, piercing jewellery, wrist watches, wrist-wear, brooches and cufflinks and parts used for jewellery-making 0.05% (by weight of the individual part)

2.Organotin compounds content

Test Method: Organic solvent extraction, GCMS
Ref. to ISO/TS 16179:2012

			Test No.	T001	T002
			Material No.	A006	A007 + A008 + A009
Test Parameter	Unit	RL	Regulatory Requirement	Result	Result
TBT(Tributyltin) by weight of tin	%	0.01	--	< RL	< RL
TPT(Triphenyltin) by weight of tin	%	0.01	--	< RL	< RL
TOT(Trioctyltin) by weight of tin	%	0.01	--	< RL	< RL
TCyT(Tricyclohexyltin) by weight of tin	%	0.01	--	< RL	< RL
TPrT(Tripropyltin) by weight of tin	%	0.01	--	< RL	< RL
Sum of Tin of tri-substituted organotins	%	NA	0.1	<RL	<RL
DBT(Dibutyltin) by weight of tin	%	0.01	0.1	< RL	< RL
DOT(Dioctyltin) by weight of tin	%	0.01	0.1	< RL	< RL
Conclusion	--	--		PASS	PASS

Abbreviation: < = less than
RL = Reporting Limit
% = percentage
NA = Not Applicable

Remark:

* Single components with an amount of <0.01% were not considered in the calculation of the sum. In the case of all five tri-substituted orgaotins were not detected, the result is stated < RL

** The assessment for tri-substituted organotins is based on the sum of TBT, TPT, TOT, TCyT and TPrT by weight of tin only.

*** According to REACH Regulation (EC) No. 1907/2006 Annex XVII Entry 20 and amendment Commission Regulation (EU) No. 276/2010 (formerly known as 2009/425/EC), organostannic compounds shall not be used or be placed on the market.

Type of organostannic compounds	Maximum Permissible Limit	Implementation date
Tri-substituted organostannic compounds, e.g. tributyltin (TBT) compounds and triphenyltin (TPT) compounds	0.1 % by weight of tin	1 July 2010
Dibutyltin (DBT) compounds in mixtures and articles for supply to the general public	0.1 % by weight of tin	1 January 2012 The below products will not be applicable until 1 January 2015: - one-component and two-component room temperature vulcanisation sealants (RTV-1 and RTV-2 sealants) and adhesives, - paints and coatings containing DBT compounds as catalysts when applied on articles, - soft polyvinyl chloride (PVC) profiles whether by themselves or coextruded with hard PVC, - fabrics coated with PVC containing DBT compounds as stabilisers when intended for outdoor applications, - outdoor rainwater pipes, gutters and fittings, as well as covering material for roofing and facades
Dioctyltin (DOT) compounds - textile articles intended to come into contact with the skin, - gloves, - footwear or part of footwear intended to come into contact with the skin, - wall and floor coverings - childcare articles, - female hygiene products, - nappies, - two-component room temperature vulcanisation moulding kits (RTV-2 moulding kits)	0.1 % by weight of tin	1 January 2012

3. Polybrominated biphenyls (PBB)

Test method : Ref. to IEC 62321-6:2015

Test result:

Test No.	Material No.	Test Parameter	Unit	Regulatory requirement	Test Result	Conclusion
T001	A006	Polybrominated biphenyls (PBBs)	%	0.1	< RL	PASS
T002	A007 + A008 + A09	Polybrominated biphenyls (PBBs)	%	0.1	< RL	PASS

Abbreviation: < = Less than
RL = Reporting Limit
% = percentage

Remark:

(*) The reporting limit for each individual PBBs are :

Reporting Limit (%)		
PBBs	Bromobiphenyl	0.0005
	Dibromobiphenyl	0.0005
	Tribromobiphenyl	0.0005
	Tetrabromobiphenyl	0.0005
	Pentabromobiphenyl	0.0005
	Hexabromobiphenyl	0.0005
	Heptabromobiphenly	0.0005
	Octabromobiphenyl	0.0005
	Nonabromobiphenyl	0.0005
	Decabromobiphenyl	0.0005

4. Phthalates content

Test Method : Ref. to CPSC-CH-C1001-09.4

Test Result:

				Test No.	T001	T002
				Material No.:	A002 + A003 + A004	A005
Test Parameter	CAS No.	Unit	RL	Regulatory Requirement	Result	Result
Diethylhexyl phthalate (DEHP)	117-81-7	%	0.005	0.1	< RL	< RL
Dibutyl phthalate (DBP)	84-74-2	%	0.005	0.1	< RL	< RL
Benzylbutyl phthalate (BBP)	85-68-7	%	0.005	0.1	< RL	< RL
Diisobutyl phthalate (DIBP)	84-69-5	%	0.005	0.1	< RL	< RL
Sum (DEHP+DBP+BBP+DIBP)	--	%	0.005	0.1	< RL	< RL
Conclusion: REACH regulation (EC) No. 1907/2006 and its amendment regulations on Annex XVII entries 51				-	Pass	Pass

Abbreviation: < = Less than
RL = Reporting Limit
% = percentage

Remark:

- Requirement of REACH regulation (EC) No. 1907/2006 and its amendment regulations on Annex XVII entries 51:

Parameter	Unit	Maximum Permissible Limit
Plasticised materials in toys and childcare articles, or other articles# place on the market;		
Diethylhexyl phthalate (DEHP) Dibutyl phthalate (DBP) Benzylbutyl phthalate (BBP) Diisobutyl phthalate (DIBP)	%	0.1 (individually or sum of the four phthalates) Effective after 7 July 2020.

Denote:
Examples of articles that are excluded from the restriction

1) Articles exclusively for industrial / agricultural use / use in open air, provided that no plasticised material comes into contact with human mucous membranes or into prolonged contact with human skin (i.e. Continuous contact of more than 10 minutes duration or intermittent contact over a period of 30 minutes, per day.)
2) Aircraft and motor vehicles (Directive 2007/46/EC) placed on the market before 7 January 2024, or articles for use exclusively in the maintenance or repair of them
3) Measuring devices for laboratory use;
4) Food contact material and articles within the scope of Regulation (EC) No 1935/2004 or Commission Regulation (EU) No 10/2011
5) Medical devices (Directive 90/385/EEC, 93/42/EEC or 98/79/EC)
6) Electrical and electronic equipment within the scope of Directive 2011/65/EU

Immediate packaging of medicinal products (Regulation (EC) No 726/2004, Directive 2001/82/EC or Directive 2001/83/EC)

5.Nonylphenol, Nonylphenolethoxylates

Test Method: NP:
For Plastics- Organic solvent extraction, GCMS
For Textiles- Organic solvent extraction, LC-MS

NPEO:
Organic solvent extraction, LC-MS

Test Result:

Test No.	Material No.	Test Parameter	Unit	RL	Test Result
T001	A006	Nonylphenol (NP)	mg/kg	5	< RL
		Nonylphenolethoxylates (NPEO)	mg/kg	20	< RL
T002	A007 + A008 + A009	Nonylphenol (NP)	mg/kg	5	< RL
		Nonylphenolethoxylates (NPEO)	mg/kg	20	< RL
T003	A010 + A011 + A012	Nonylphenol (NP)	mg/kg	5	< RL
		Nonylphenolethoxylates (NPEO)	mg/kg	20	< RL

Abbreviation: < = less than
mg/kg = milligram per kilogram
% = percentage
RL = Reporting Limit
NA = Not Applicable
0.1% = 1000mg/kg

Remark:

* The requirement is following REACH regulation (EC) No. 1907/2006 and amendment no. 552/2009 Annex XVII Entry 46:

Nonylphenol and nonylphenol ethoxylates shall not be placed on the market, or used, as substances or in mixtures in concentrations equal to or greater than 0,1 % by weight for the following purposes:
(1) Industrial and institutional cleaning;
(2) Domestic cleaning;
(3) Textiles and leather processing;
(4) Emulsifier in agricultural teat dips;
(5) Metal working;
(6) Manufacturing of pulp and paper;
(7) Cosmetic products;
(8) Other personal care products;
(9) Co-formulants in pesticides and biocides.

** The requirement is following REACH regulation (EC) No. 1907/2006 and amendment no. 552/2009 and (EU) 2016/26 Annex XVII Entry 46a:

Nonylphenol ethoxylates shall not be placed on the market after 3 February 2021 in textile articles which can reasonably be expected to be washed in water during their normal lifecycle, in concentrations equal to or greater than 0,01 % by weight of that textile article or of each part of the textile article.

6.Perfluorooctanoic acid (PFOA) and its salts^

Test Method: In house method, LC-MS-MS / GC-PCIMS analysis

Test Result:

Test No.	Material No	Test Parameter	CAS no.	Unit	RL	Regulatory Requirement	Test Result
T001	A006 + A007	Potassiumperfluorooctanoate (K-PFOA)*	2395-00-8	ppb	10	25	< RL
		Perfluorooctane carboxylate (PFOA)*	335-67-1	ppb			
		Silverperfluorooctanoate (Ag-PFOA)*	335-93-3	ppb			
		Sodiumperfluorooctanoate (Na-PFOA)*	335-95-5	ppb			
		Ammonium pentadecafluorooctanoate (APFO)*	3825-26-1	ppb			

Test No.	Material No	Test Parameter	CAS no.	Unit	RL	Regulatory Requirement	Test Result
T002	A008 + A009	Potassiumperfluorooctanoate (K-PFOA)*	2395-00-8	ppb	10	25	< RL
		Perfluorooctane carboxylate (PFOA)*	335-67-1	ppb			
		Silverperfluorooctanoate (Ag-PFOA)*	335-93-3	ppb			
		Sodiumperfluorooctanoate (Na-PFOA)*	335-95-5	ppb			
		Ammonium pentadecafluorooctanoate (APFO)*	3825-26-1	ppb			

Test No.	Material No	Test Parameter	CAS no.	Unit	RL	Regulatory Requirement	Test Result
T003	A010	Potassiumperfluorooctanoate (K-PFOA)*	2395-00-8	ppb	10	25	< RL
		Perfluorooctane carboxylate (PFOA)*	335-67-1	ppb			
		Silverperfluorooctanoate (Ag-PFOA)*	335-93-3	ppb			
		Sodiumperfluorooctanoate (Na-PFOA)*	335-95-5	ppb			
		Ammonium pentadecafluorooctanoate (APFO)*	3825-26-1	ppb			

Test Report No.: 178141074a 001

Test No.	Material No	Test Parameter	CAS no.	Unit	RL	Regulatory Requirement	Test Result
T004	A011 + A012	Potassiumperfluorooctanoate (K-PFOA)*	2395-00-8	ppb	10	25	< RL
		Perfluorooctane carboxylate (PFOA)*	335-67-1	ppb			
		Silverperfluorooctanoate (Ag-PFOA)*	335-93-3	ppb			
		Sodiumperfluorooctanoate (Na-PFOA)*	335-95-5	ppb			
		Ammonium pentadecafluorooctanoate (APFO)*	3825-26-1	ppb			

Abbreviation: < = less than
RL = Reporting Limit
ppb = Parts per billion

Remark:

* Tested with the equivalence of pentadecafluorooctanoate

** According to REACH regulation (EC) No. 1907/2006 Annex XVII Entry 68 and amendment Commission Regulation (EU) No. 2017/1000. PFOA and its salts shall not be used in a concentration equal to or above 25 ppb or one or a combination of PFOA-related substances shall not be used in a concentration equal to or above 1000ppb in the production of, or placed on the market in another substance, as a constituent; a mixture; an article.

*** Single component with an amount below reporting limit was not considered by the calculation of the sum. In the case of all above substances were not detected, the result is stated < RL

7. Screening of substances of very high concern (SVHC) subject to authorisation, according to (EU) No 143/2011, (EU) No 125/2012, (EU) No 348/2013, (EU) No 895/2014 , (EU) No. 2017/999 and (EU) No. 2020/171 and candidate list by European Chemical Agency (ECHA), according to the EU Court of Justice rules on SVHCs in articles.

Product Classification

With reference to Corrigendum to Regulation (EC) no.1907/2006 and ECHA, this product is classified as:

[X] Article

[ ] Article with an integral substance/ mixture

[ ] Combinations of an article (functioning as a container or a carrier material) and a substance/ mixture

[ ] Substance/ mixture

Conclusion:

Conclusion			
Product Location	Acc. to **authorisation list (EU) No 143/2011, (EU) No 125/2012, (EU) No 348/2013 , (EU) No 895/2014, (EU) No. 2017/999 and (EU) No. 2020/171 (Annex XIV of EC No 1907/2006) and candidate list by ECHA, and the EU Court of Justice rules on SVHCs in articles,** the detected SVHC concentration in components level is	**Obligation of Importer (*) (For article)**	**Detected Substance (if any)**
A001	<0.1%	Not necessary	/
A002 + A003 + A004	<0.1%	Not necessary	/
A005	<0.1%	Not necessary	/
A006 + A007 + A008 + A009 + A010 + A011 + A012	<0.1%	Not necessary	/

(For article)
(*) To communicate information down the supply chain according to article. 33 of REACH. **OR**
1. Notification to ECHA, if the quantities of SVHC in the produced/imported articles are above 1 ton in total per year per company.
2. Provide sufficient information to ensure safe use of the article and, as a minimum, include the name of the substance, to their customers and on request to consumers within 45 days of the receipt of this request.

Test Report No.: 178141074a 001

Test Results

Screening of substances of very high concern (SVHC) subject to authorisation, according to (EU) No 143/2011, (EU) No 125/2012, (EU) No 348/2013, (EU) No 895/2014, (EU) No. 2017/999 and (EU) No. 2020/171 (Annex XIV of EC No 1907/2006) and candidate list by European Chemical Agency (ECHA), according to the EU Court of Justice rules on SVHCs in articles.

Test Method: 1) Test portion is digested with acid and assisted with microwave, the elements are analysed by ICP-OES.
2) Test portion is extracted by organic solvent, semi-quantitative analysis by GC-MS / UV-Vis.
3) Test portion is extracted by organic solvent, the extraction solution is analyzed by Headspace-GC/MS / LC-DAD-MS / LC-MS/MS.

Test No.:	T001	T002	T003
Material No.:	A001	A002 + A003 + A004	A005
Result (%)	< RL	< RL	< RL

Test No.:	T004
Material No.:	A006 + A007 + A008 + A009 + A010 + A011 + A012
Result (%)	< RL

Abbreviation: < = Less than
RL =Reporting Limit
% =Percentage

Remark:

(*1) The reporting limit for each individual SVHC subject to authorisation according to (EU) No 143/2011, (EU) No 125/2012, (EU) No 348/2013, (EU) No 895/2014, (EU) No. 2017/999 and (EU) No. 2020/171 (Annex XIV of EC No 1907/2006):

	Substance	CAS No.	Reporting Limit
1	4,4'- Diaminodiphenylmethane (MDA)	101-77-9	0.01%
2	Benzyl butyl phthalate (BBP)	85-68-7	0.01%
3	Bis (2-ethylhexyl)phthalate (DEHP)	117-81-7	0.01%
4	Dibutyl phthalate (DBP)	84-74-2	0.01%
5	Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified: Alpha-hexabromocyclododecane Beta-hexabromocyclododecane Gamma-hexabromocyclododecane	25637-99-4 / 3194-55-6 / 134237-50-6 / 134237-51-7 / 134237-52-8	0.01%
6	5-tert-butyl-2,4,6-trinitro-m-xylene (Musk xylene)	81-15-2	0.01%
7	2,4-Dinitrotoluene (2,4-DNT)	121-14-2	0.01%
8	Diisobutyl phthalate (DIBP)	84-69-5	0.01%
9	Tris(2-chloroethyl)phosphate	115-96-8	0.01%
10	Diarsenic pentaoxide (*3)	1303-28-2	0.01%
11	Diarsenic trioxide (*3)	1327-53-3	0.01%
12	Lead chromate (*3)(*4)	7758-97-6	0.01%
13	Lead chromate molybdate sulphate red (C.I. Pigment Red 104) (*3)(*4)	12656-85-8	0.01%
14	Lead sulfochromate yellow (C.I. Pigment Yellow 34) (*3)	1344-37-2	0.01%
15	Trichloroethylene	79-01-6	0.01%
16	Chromium trioxide (*4)	1333-82-0	0.01%

17	Acids generated from chromium trioxide and their oligomers: Names of the acids and their oligomers: Chromic acid, Dichromic acid, Oligomers of chromic acid and dichromic acid. (*4)	7738-94-5 / 13530-68-2	0.01%
18	Sodium dichromate (*3)	7789-12-0 / 10588-01-9	0.01%
19	Potassium dichromate (*4)	7778-50-9	0.01%
20	Ammonium dichromate (*4)	7789-09-5	0.01%
21	Potassium chromate (*4)	7789-00-6	0.01%
22	Sodium chromate (*4)	7775-11-3	0.01%
23	Formaldehyde, oligomeric reaction products with aniline (technical MDA) (*11)	25214-70-4	0.01%
24	1,2-Dichloroethane	107-06-2	0.01%
25	Bis(2-methoxyethyl) ether	111-96-6	0.01%
26	Arsenic acid (*3)	7778-39-4	0.01%
27	2,2'-dichloro-4,4'-methylenedianiline (MOCA)	101-14-4	0.01%
28	Dichromium tris(chromate) (*4)	24613-89-6	0.01%
29	Strontium chromate (*4)	7789-06-2	0.01%
30	Potassium hydroxyoctaoxodizincatedichromate (*4)	11103-86-9	0.01%
31	Pentazinc chromate octahydroxide (*4)	49663-84-5	0.01%
32	1-bromopropane (n-propyl bromide)	106-94-5	0.01%
33	Diisopentylphthalate	605-50-5	0.01%
34	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich (DIHP)	71888-89-6	0.01%
35	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP)	68515-42-4	0.01%
36	1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	84777-06-0	0.01%
37	Bis(2-methoxyethyl) phthalate	117-82-8	0.01%
38	Dipentyl phthalate (DPP)	131-18-0	0.01%
39	N-pentyl-isopentylphthalate	776297-69-9	0.01%
40	Anthracene oil (*7)	90640-80-5	0.01%
41	Pitch, coal tar, high temperature (*7)	65996-93-2	0.01%
42	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (OPEO) *[covering well-defined substances and UVCB substances, polymers and homologues]*	-	0.01%
43	4-Nonylphenol, branched and linear *[substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof]*	-	0.01%
44	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	68515-50-4	0.01%
45	Dihexyl phthalate	84-75-3	0.01%
46	1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate (EC No. 201-559-5)	68515-51-5 / 68648-93-1	0.01%
47	Trixylyl phosphate	25155-23-1	0.01%
48	Sodium perborate,perboric acid, sodium salt (*3) (*6)	-	0.01%
49	Sodium peroxometaborate (*3) (*6)	7632-04-4	0.01%
50	5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof]	-	0.01%
51	2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)	25973-55-1	0.01%
52	2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327)	3864-99-1	0.01%

53	2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350)	36437-37-3	0.01%
54	2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)	3846-71-7	0.01%

(*2) The reporting limit for each individual SVHC in Candidate List by ECHA:

	Substance	CAS No.	Reporting Limit
55	Anthracene	120-12-7	0.01%
56	Bis(tributyltin) oxide (TBTO) (*3) (*5)	56-35-9	0.01%
57	Triethyl arsenate (*3)	15606-95-8	0.01%
58	Lead hydrogen arsenate (*3)	7784-40-9	0.01%
59	Cobalt dichloride (*3)	7646-79-9	0.01%
60	Acrylamide	79-06-1	0.01%
61	Anthracene oil, anthracene paste, distn. lights (*7)	91995-17-4	0.01%(*8)
62	Anthracene oil, anthracene paste, anthracene fraction (*7)	91995-15-2	
63	Anthracene oil, anthracene-low (*7)	90640-82-7	
64	Anthracene oil, anthracene paste (*7)	90640-81-6	
65	Boric acid (*3) (*6)	10043-35-3 / 11113-50-1	0.01%
66	Disodium tetraborate, anhydrous (*3) (*6)	1303-96-4 / 1330-43-4 / 12179-04-3	0.01%
67	Tetraboron disodium heptaoxide, hydrate (*3) (*6)	12267-73-1	0.01%
68	2-Methoxyethanol	109-86-4	0.01%
69	2-Ethoxyethanol	110-80-5	0.01%
70	Cobalt(II) sulphate (*3)	10124-43-3	0.01%
71	Cobalt(II) dinitrate (*3)	10141-05-6	0.01%
72	Cobalt(II) carbonate (*3)	513-79-1	0.01%
73	Cobalt(II) diacetate (*3)	71-48-7	0.01%
74	Alkanes C10-C13, chloro (Short Chain Chlorinated Paraffins) (SCCP)	85535-84-8	0.01%
75	2-Ethoxyethyl acetate	111-15-9	0.01%
76	Hydrazine	302-01-2 / 7803-57-8	0.01%
77	1-Methyl-2-pyrrolidone (NMP)	872-50-4	0.01%
78	1,2,3-Trichloropropane	96-18-4	0.01%
79	Aluminosilicate Refractory Ceramic Fibres (RCF) (*9)	-	0.01%
80	Zirconia Aluminosilicate Refractory Ceramic Fibres (Zr-RCF) (*9)	-	0.01%
81	2-Methoxyaniline,o-Anisidine	90-04-0	0.01%
82	4-(1,1,3,3-tetramethylbutyl)phenol	140-66-9	0.01%
83	Calcium arsenate (*3)	7778-44-1	0.01%
84	Trilead diarsenate (*3)	3687-31-8	0.01%
85	N,N-dimethylacetamide (DMAC)	127-19-5	
86	Phenolphthalein	77-09-8	0.01%
87	Lead dipicrate (*3)	6477-64-1	0.01%
88	Lead diazide, Lead azide (*3)	13424-46-9	0.01%
89	Lead styphnate (*3)	15245-44-0	0.01%

90	1,2-bis(2-methoxyethoxy)ethane (TEGDME,triglyme)	112-49-2	0.01%
91	1,2-dimethoxyethane,ethylene glycol dimethyl ether (EGDME)	110-71-4	0.01%
92	Diboron trioxide (*3) (*6)	1303-86-2	0.01%
93	Formamide	75-12-7	0.01%
94	Lead(II) bis(methanesulfonate) (*3)	17570-76-2	0.01%
95	1,3,5-Tris(oxiran-2-ylmethyl)-1,3,5-triazinane-2,4,6-trione (TGIC)	2451-62-9	0.01%
96	1,3,5-tris[(2S and 2R)-2,3-epoxypropyl]-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione (β-TGIC)	59653-74-6	0.01%
97	4,4'-bis(dimethylamino)benzophenone (Michler's ketone), MK	90-94-8	0.05%
98	N,N,N',N'-tetramethyl-4,4'-methylenedianiline (Michler's base), RMK	101-61-1	0.01%
99	[4-[[4-anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene] cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride (C.I. Basic Blue 26) [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)] (*10)	2580-56-5	0.01%
100	[4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride (C.I. Basic Violet 3) [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)] (*10)	548-62-9	
101	4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)] (*10)	561-41-1	
102	α,α-Bis[4-(dimethylamino)phenyl]-4 (phenylamino)naphthalene-1-methanol (C.I. Solvent Blue 4) [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)] (*10)	6786-83-0	
103	Bis(pentabromophenyl) ether (decabromodiphenyl ether) (DecaBDE)	1163-19-5	0.01%
104	Pentacosafluorotridecanoic acid	72629-94-8	0.01%
105	Tricosafluorododecanoic acid	307-55-1	0.01%
106	Henicosafluoroundecanoic acid	2058-94-8	0.01%
107	Heptacosafluorotetradecanoic acid	376-06-7	0.01%
108	Diazene-1,2-dicarboxamide (C,C'-azodi(formamide)) (ADCA) (*12)	123-77-3	0.05%
109	Cyclohexane-1,2-dicarboxylic anhydride [1], cis-cyclohexane-1,2-dicarboxylic anhydride [2], trans-cyclohexane-1,2-dicarboxylic anhydride [3] [The individual cis- [2] and trans- [3] isomer substances and all possible combinations of the cis- and trans-isomers [1] are covered by this entry]	85-42-7 / 13149-00-3 / 14166-21-3	0.01%
110	Hexahydromethylphthalic anhydride (MHHPA) [1], Hexahydro-4-methylphthalic anhydride [2], Hexahydro-1-methylphthalic anhydride [3], Hexahydro-3-methylphthalic anhydride [4] [The individual isomers [2], [3] and [4] (including their cis- and trans- stereo isomeric forms) and all possible combinations of the isomers [1] are covered by this entry]	25550-51-0 / 19438-60-9 / 48122-14-1 / 57110-29-9	0.01%
111	N,N-dimethylformamide	68-12-2	0.01%
112	1,2-Diethoxyethane	629-14-1	0.01%
113	Diethyl sulphate	64-67-5	0.01%

114	Methoxyacetic acid (MAA)	625-45-6	0.01%
115	Dimethyl sulphate	77-78-1	0.01%
116	N-methylacetamide	79-16-3	0.01%
117	Furan	110-00-9	0.01%
118	Methyloxirane (Propylene oxide)	75-56-9	0.01%
119	3-ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine	143860-04-2	0.01%
120	Dibutyltin dichloride (DBTC) (*3)	683-18-1	0.01%
121	Dinoseb (6-sec-butyl-2,4-dinitrophenol)	88-85-7	0.01%
122	4,4'-methylenedi-o-toluidine	838-88-0	0.01%
123	4,4'-oxydianiline and its salts	101-80-4	0.01%
124	4-Aminoazobenzene	60-09-3	0.01%
125	4-methyl-m-phenylenediamine (toluene-2,4-diamine)	95-80-7	0.01%
126	6-methoxy-m-toluidine (p-cresidine)	120-71-8	0.01%
127	Biphenyl-4-ylamine	92-67-1	0.01%
128	o-aminoazotoluene	97-56-3	0.01%
129	o-Toluidine	95-53-4	0.01%
130	Acetic acid, lead salt, basic (*3)	51404-69-4	0.01%
131	Trilead bis(carbonate) dihydroxide (*3)	1319-46-6	0.01%
132	Lead oxide sulfate (*3)	12036-76-9	0.01%
133	[Phthalato(2-)]dioxotrilead (*3)	69011-06-9	0.01%
134	Dioxobis(stearato)trilead (*3)	12578-12-0	0.01%
135	Fatty acids, C16-18, lead salts (*3)	91031-62-8	0.01%
136	Lead bis(tetrafluoroborate) (*3)	13814-96-5	0.01%
137	Lead cyanamidate (*3)	20837-86-9	0.01%
138	Lead dinitrate (*3)	10099-74-8	0.01%
139	Lead monoxide (lead oxide) (*3)	1317-36-8	0.01%
140	Orange lead (lead tetroxide) (*3)	1314-41-6	0.01%
141	Lead titanium trioxide (*3)	12060-00-3	0.01%
142	Lead titanium zirconium oxide (*3)	12626-81-2	0.01%
143	Pyrochlore, antimony lead yellow (*3)	8012-00-8	0.01%
144	Pentalead tetraoxide sulphate (*3)	12065-90-6	0.01%
145	Silicic acid ($H_2Si_2O_5$), barium salt (1:1), lead-doped *[with lead (Pb) content above the applicable generic concentration limit for 'toxicity for reproduction' Repr. 1A (CLP) or category 1 (DSD),the substance is a member of the group entry of lead compounds, with index number 082-001-00-6 in Regulation (EC) No 1272/2008]* (*3)	68784-75-8	0.01%
146	Silicic acid, lead salt (*3)	11120-22-2	0.01%
147	Sulfurous acid, lead salt, dibasic (*3)	62229-08-7	0.01%
148	Tetraethyllead (*3)	78-00-2	0.01%
149	Tetralead trioxide sulphate (*3)	12202-17-4	0.01%
150	Trilead dioxide phosphonate (*3)	12141-20-7	0.01%
151	Ammonium pentadecafluorooctanoate (APFO) (*13)	3825-26-1	0.01%
152	Pentadecafluorooctanoic acid (PFOA)	335-67-1	0.01%
153	Cadmium (*3)	7440-43-9	0.01%
154	Cadmium oxide (*3)	1306-19-0	0.01%
155	4-Nonylphenol, branched and linear, ethoxylated (NPEO) [*substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof*]	-	0.01%
156	Imidazolidine-2-thione; (2-imidazoline-2-thiol)	96-45-7	0.01%

157	Disodium 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis(4-aminonaphthalene-1-sulphonate) (C.I. Direct Red 28)	573-58-0	0.01%
158	Disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate (C.I. Direct Black 38)	1937-37-7	0.01%
159	Lead di(acetate) (*3)	301-04-2	0.01%
160	Cadmium sulphide (*3)	1306-23-6	0.01%
161	Cadmium chloride (*3)	10108-64-2	0.01%
162	Cadmium fluoride (*3)	7790-79-6	0.01%
163	Cadmium sulphate (*3)	10124-36-4 / 31119-53-6	0.01%
164	2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE) (*14)	15571-58-1	0.01%
165	Reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE) (*15)	-	0.01%
166	1,3-propanesultone	1120-71-4	0.01%
167	Nitrobenzene	98-95-3	0.01%
168	Perfluorononan-1-oic-acid and its sodium and ammonium salts	375-95-1 21049-39-8 4149-60-4	0.01%
169	Benzo[def]chrysene (Benzo[a]pyrene)	50-32-8	0.01%
170	4,4'-isopropylidenediphenol (bisphenol A)	80-05-7	0.01%
171	Nonadecafluorodecanoic acid (PFDA) and its sodium and ammonium salts	335-76-2 3830-45-3 3108-42-7	0.01%
172	4-heptylphenol, branched and linear [substances with a linear and/or branched alkyl chain with a carbon number of 7 covalently bound predominantly in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof]	-	0.01%
173	*p*-(1,1-dimethylpropyl)phenol	80-46-6	0.01%
174	Perfluorohexane-1-sulfonic acid and its salts (PFHxS)	-	0.01%
175	Chrysene	218-01-9	0.01%
176	Benzo[a]anthracene	56-55-3	0.01%
177	Cadmium nitrate(*3)	10325-94-7	0.01%
178	Cadmium hydroxide(*3)	21041-95-2	0.01%
179	Cadmium carbonate(*3)	513-78-0	0.01%
180	1,6,7,8,9,14,15,16,17,17,18,18- Dodecachloropentacyclo [12.2.1.16,9.02,13.05,10]octadeca-7,15-diene ("Dechlorane Plus"TM) [covering any of its individual anti- and syn-isomers or any combination thereof]	-	0.01%
181	Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP) [with ≥0.1% w/w 4-heptylphenol, branched and linear]	-	0.01%
182	Benzene-1,2,4-tricarboxylic acid 1,2 anhydride (trimellitic anhydride, TMA)	552-30-7	0.01%
183	Dicyclohexyl phthalate (DCHP)	84-61-7	0.01%
184	Terphenyl, hydrogenated	61788-32-7	0.01%
185	Octamethylcyclotetrasiloxane (D4)	556-67-2	0.01%
186	Decamethylcyclopentasiloxane (D5)	541-02-6	0.01%
187	Dodecamethylcyclohexasiloxane (D6)	540-97-6	0.01%
188	Ethylenediamine (EDA)	107-15-3	0.01%
189	Lead	7439-92-1	0.01%
190	Disodium octaborate (*3)	12008-41-2	0.01%
191	Benzo[ghi]perylene	191-24-2	0.01%
192	2,2-bis(4'-hydroxyphenyl)-4-methylpentane	6807-17-6	0.01%
193	Benzo[k]fluoranthene	207-08-9	0.01%

194	Fluoranthene	206-44-0	0.01%
195	Phenanthrene	85-01-8	0.01%
196	Pyrene	129-00-0	0.01%
197	1,7,7-trimethyl-3-(phenylmethylene)bicyclo[2.2.1]heptan- 2-one	15087-24-8	0.01%
198	2-methoxyethyl acetate	110-49-6	0.01%
199	Tris(4-nonylphenyl, branched and linear) phosphite (TNPP) with ≥ 0.1% w/w of 4-nonylphenol, branched and linear (4-NP)	-	0.01%
200	2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acyl halides (covering any of their individual isomers and combinations thereof)	-	0.01%
201	4-tert-butylphenol	98-54-4	0.01%
202	Diisohexyl phthalate (DiHexP)	71850-09-4	0.01%
203	2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone	119313-12-1	0.01%
204	2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one	71868-10-5	0.01%
205	Perfluorobutane sulfonic acid (PFBS) and its salts	-	0.01%

Remark:

(*3) The substances are tested and calculated in terms of its respective elements and to the worst-case scenario.And the elements may come from the compounds other than SVHCs.

(*4) The substances are tested and calculated in terms of Cr (VI).

(*5) The substance is tested and calculated in terms of Tributyl tin.

(*6) The substances are confirmed and tested in terms of borate. Boric acid, Disodium tetraborate, anhydrous, Tetraboron disodium heptaoxide, hydrate and Diboron trioxide, Sodium perborate,perboric acid, sodium salt, Sodium peroxometaborate are detected as sum of boric acid. And the borate may come from the compounds other than SVHCs.

(*7) The substances are UVCB (substance of unknown or variable composition, complex reaction products or biological materials), which are identified by its main constituents.

(*8) Individual concentrations to the constituent of UVCB with an amount of < 0.01% were not considered by the calculation of the sum.

(*9) The test results are based on microscopic and chemical evaluation.

(*10) The substances are quantified in terms of Michler's ketone and Michler's base by LC-MS, as Michler's ketone or Michler's base was found exceeds 0.01%.

(*11) The content oligomer is determined by Py-GC/MS.

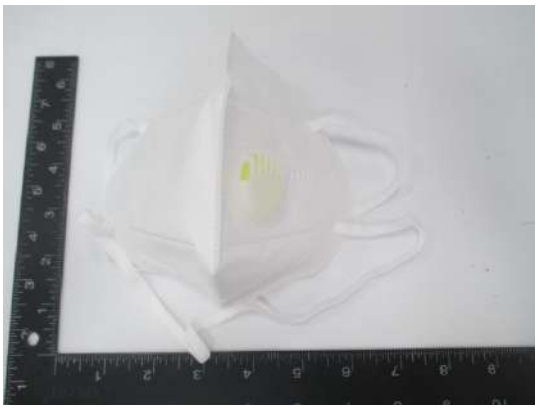
(*12) The content of diazene-1,2-dicarboxamide is analyzed in terms of its breakdown product.

(*13) The substance is tested in terms of pentadecafluorooctanoate.

(*14) The substance is tested and calculated in terms of Dioctyl tin.

(*15) The substance is tested and calculated in terms of Monooctyl tin and Dioctyl tin.

Sample Photos



- END -

Technical Specification Sheet

Particle Filtering Half Mask

OM-P2195

Intended Usage:

This product, which is normally used in the general working environment, is designed to provide reliable respiratory protection of against certain airborne particles and dust, block body fluids and so on.

Product Composition:

- Polypropylene spunbonded non-woven fabric
- Polypropylene melt-blown fabric
- Plastomer+metal nose clip
- Spandex ear-belt
- Nano materials

Attention Before Use:

Please read these instructions thoroughly before use. The mask is non-re-usable particle filtering half mask. This mask is intended exclusively for the personal protection, and it is not medical face mask.

How To Use:

- Wash or disinfect hands before taking out the mask off the package. Avoid touching the inner surface of the mask.
- Hold the mask by the ear straps and get the nose and mouth inside the mask.
- Fix the ear belts around both ears.
- Hold the mask against your chin with the back of one hand.
- Place the fingers of both hands in the middle of the nose clip, while pressing inwards.
- Move the finger tips along the nose clip to both sides, and press the nose clip into the shape of nose bridge completely.
- Do not touch the mask while in use. If so, wash or disinfect your hands.

Instructions to remove and discard the mask:

- To remove the mask, use thumbs and index fingers to remove both ear straps
- Carefully dispose the used mask adequately
- Wash or disinfect hands

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Technical Specification Sheet

Cautions and Warning:

- Please check the integrity and validity of the package before use. If the package is damaged, don't use it.
- Prior to use, pls. check fit of particle filtering half mask.
- It is unlikely that the requirements for leakage will be achieved if facial hair passes under the face.
- Pls. note air quality (contaminants, oxygen deficiency).
- Do not use it in explosive atmosphere.
- Pls. note that the particle filtering half mask shall not be used for more than one shift.
- This product is disposable. Please treat it according to the local environmental protection requirements after use, and do not discard it at will.

Model:

OM-P2195

Specifications:

10.5cm *16.5 cm (after folding)

Shelf Life:

Three Years after the production date

Symbols:

				
Shelf Life	Temperature Range of storage conditions	Maximum Relative humidity of storage conditions	See information Supplied by The manufacturer	CE Mark

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