IVROU®

DISPOSABLE MEDICAL MASK

EN 14683:2019+AC:2019 TYPE IIR

ST-KZ-01

175 × 95mm

Ear Loop / Blue

CE

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IVROU®

SGS

Proposal No.: CN/MDD/I/TCF/2020-038

Medical Device File Review Report

Report No.:	SGS/CN/SZX-IT20045/001
Applicant:	Guangzhou Shuter Technology Co., Ltd.
Address:	No.882 South of Gongye Dadao, Haizhu District, Guangzhou City, Guangdong Province, P.R. China
Product(s) Name:	Disposable Medical Mask
Type(s)/Model(s):	ST-KZ-01, ST-KZ-03
Classification:	Class I not sterile or measuring under Directive 93/42/EEC (according to the manufacturer's declaration)
Review Purpose:	Review the completeness of the Technical Documentation in accordance with the requirements of Annex VII of Directive 93/42/EEC as amended by 2007/47/EC
Review Result:	During the review of the Technical Documentation **(ST-TF-FM, Ver.1.1, 20/04/2020)** provided for the above listed product(s), no non-compliance was detected according to the requirements of Annex VII of Directive 93/42/EEC
Date of Review:	2020-04-20
Date of Expire:	2021-04-19

Mendy Zhang
Deputy Director, Medical Device

Disclaimer: This report relates only to the product(s) as described in the Technical Documentation on the date and version shown. Conformance to all the regulatory requirements is the sole responsibility of the manufacturer including the manufacture, quality control, safety and performance of the product(s).

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IVROU®

EC Declaration of Conformity

Document No. ST-TF-FM-020
Version 01

Manufacture: Guangzhou Shuter Technology Co., Ltd
Address: No.882 South of Gongye Dadao, Haizhu District, Guangzhou City, Guangdong Province, P.R. China

We declare under our sole responsibility that:

Product Name: Disposable Medical Mask
Brand name: Shuter Life
Model: ST-KZ-01, ST-KZ-03
Product Type: EN14683:2019+AC:2019, Type IIR
Class: Class I based on Rule 1 in Annex IX 93/42/EEC

Meets the provisions of EC directive 93/42/EEC and its transpositions in national laws which apply to it. The designated product with directive 93/42/EEC has been assessed by the manufacture following the procedure relating to the EC declaration of conformity set out in Annex VII of 93/42/EEC. And affix the CE mark. the technical file report has been assessed as meeting the essential requirement (Annex I) of EC directive 93/42/EEC as amended by 2007/47/EC. The declaration is valid in connection with the "Technical file review report" of the device from SGS Academy.

EU Authorized Representative:

Company Name: CMC Medical Devices & Drugs S.L

Company Address: C/Horacio Lengo Nº 18 CP 29006, Málaga-Spain

Technical file review report No.: SGS/CN/SZX-IT20045/001

Guangzhou 2020.5.15
Place. Date

Chen Huixuan.
Name and function of manufacture

General manager.
Position

Report No.: **168265888a 001**

Client: **GUANGZHOU SHUTER TECHNOLOGY CO., LTD**

Contact Information: #,9No.882 South of Gongye Dadao, Haizhu District, Guangzhou City, Guangdong Province, China

Test item(s): 12 Materials

Identification/ Model No(s): Disposable medical mask(non sterile)
ST-KZ-01, ST-KZ-03

Sample Receiving date: 2020-05-21

Testing Period: 2020-05-25 to 2020-05-28

Test Specification:	*Test result:*
1. Customer's requirement: 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)	PASS
2. Polycyclic aromatic hydrocarbons (PAHs)	PASS
3. Total Lead Content	PASS
4. NP and NPEO Content	PASS
5. Organotin Compounds Content	PASS
6. Total Cadmium Content	PASS
7. Flame Retardants Content	PASS
8. Banned azo dyes	PASS
9. Phthalates Content	PASS

Other information:

1)17.5cm x 9.5cm
2)14.5cm x 9.5cm

For and on behalf of
TÜV Rheinland (Shenzhen) Co., Ltd.

Aaliya Chen

2020-05-29 Aaliya Chen / Assistant Project Manager

Date *Name/Position*

Sample information is provided by customer. Test result is drawn according to the kind and extent of tests performed. This test report relates to the above mentioned 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:

Item: Disposable medical mask(non sterile)

ST-KZ-01, ST-KZ-03

Material No.	Material	Color	Location
M001	Metal	Silvery	Refer to photo
M002	Plastic	White	Refer to photo
M003	Textile	Blue	Refer to photo
M004	Plastic + Textile	White	Refer to photo
M005	Textile	White	Refer to photo
M006	Plastic + Textile	White	Refer to photo
M007	Metal	Silvery	Refer to photo
M008	Plastic	White	Refer to photo
M009	Textile	Blue	Refer to photo
M010	Plastic + Textile	White	Refer to photo
M011	Textile	White	Refer to photo
M012	Plastic + Textile	White	Refer to photo

1. 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 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) SVOC: organic solvent extraction, determination by GC-MS/ECD
^2) VOC: organic solvent extraction, determination by GC-MS
^3) VVOC: headspace-GC/MS analysis
^4) non-VOC: organic solvent extraction, determination by LC-MS/MS.
^5) inorganics: acid digestion, determination by ICP-OES

Test No.:	T001	T002	T003
Material No.:	M001	M007	M002 + M003 + M004 + M005 + M006
Result (%)	< RL	< RL	< RL

Test No.:	T004
Material No.:	M008 + M009 + M010 + M011 + M012
Result (%)	< RL

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

Remark:

The tested material(s) was screened only for selected SVHCs. Selection of tests refers to the material type and application and the possibility of contamination during production & material specific contamination of the product.
SVHC which are not mentioned in test result were either not subject to testing or not detected.

(*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	

85	N,N-dimethylacetamide (DMAC)	127-19-5	0.01%
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 (H2Si2O5), 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%

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.

(*16) The tested material(s) was screened only for selected SVHCs. Selection of tests refers to the material type and application and the possibility of contamination during production & material specific contamination of the product.

(*17) The other SVHCs which are not mentioned in test result were either not subject to testing according to remark *16 or not detected.

2.^Polycyclic aromatic hydrocarbons (PAHs)

Test Method: Organic solvent extraction, GCMS

				Test No.	T001	T002	T003
				Material No.	M002 + M004 + M006	M003 + M005	M008 + M010 + M012
Test Parameter	CAS NO	Unit	RL	Regulatory Requirement	Result	Result	Result
Benzo[a]anthracene (BaA)	56-55-3	mg/kg	0.2	1	< RL	< RL	< RL
Benzo[a]pyrene(BaP)	50-32-8	mg/kg	0.2	1	< RL	< RL	< RL
Benzo[b]fluoranthene (BbFA)	205-99-2	mg/kg	0.2	1	< RL	< RL	< RL
Benzo[k]fluoranthene (BkFA)	207-08-9	mg/kg	0.2	1	< RL	< RL	< RL
Benzo[j]fluoranthene (BjFA)	205-82-3	mg/kg	0.2	1	< RL	< RL	< RL
Benzo[e]pyrene (BeP)	192-97-2	mg/kg	0.2	1	< RL	< RL	< RL
Chrysene (CHR)	218-01-9	mg/kg	0.2	1	< RL	< RL	< RL
Dibenzo[a,h]anthracene (DBAhA)	53-70-3	mg/kg	0.2	1	< RL	< RL	< RL

				Test No.	T004
				Material No.	M009 + M011
Test Parameter	CAS NO	Unit	RL	Regulatory Requirement	Result
Benzo[a]anthracene (BaA)	56-55-3	mg/kg	0.2	1	< RL
Benzo[a]pyrene(BaP)	50-32-8	mg/kg	0.2	1	< RL
Benzo[b]fluoranthene (BbFA)	205-99-2	mg/kg	0.2	1	< RL
Benzo[k]fluoranthene (BkFA)	207-08-9	mg/kg	0.2	1	< RL
Benzo[j]fluoranthene (BjFA)	205-82-3	mg/kg	0.2	1	< RL
Benzo[e]pyrene (BeP)	192-97-2	mg/kg	0.2	1	< RL
Chrysene (CHR)	218-01-9	mg/kg	0.2	1	< RL
Dibenzo[a,h]anthracene (DBAhA)	53-70-3	mg/kg	0.2	1	< RL

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

Remark:

* Requirement according to REACH regulation (EC) No. 1907/2006 with Amendment No. 552/2009 Annex XVII Item No. 50 and (EU) No.1272/2013, are summarized as below:

Scope	Parameter	Unit	Maximum permissible limit
Articles with direct as well as prolonged or short-term repetitive contact with the human skin or the oralcavity, under normal or reasonably foreseeable conditions of use ,made of plastic and rubber shall follow below limit:			
Such articles include amongst others: ---sport equipment such as bicycles, golf clubs, racquets ---household utensils, trolleys, walking frames --- tools for domestic use --- clothing, footwear, gloves and sportswear ---watch-straps, wrist-bands, masks, head-bands	Each of 8 listed PAHs	mg/kg	1
Toys, including activity toys, and childcare articles	Each of 8 listed PAHs	mg/kg	0.5

3.^Total Lead

Test Method: CPSC-CH-E1001-08.3, CPSC-CH-E1002-08.3 and CPSC-CH-E1003-09.1 (Microwave method)

Test result:

Test No.	Material No.	Test Parameter	Unit	RL	Regulatory Requirement	Test Result
T001	M001	Lead Content	%	0.001	0.05	< RL
T002	M007	Lead Content	%	0.001	0.05	< RL
T003	M002 + M004 + M006	Lead Content	%	0.001	0.05	< RL
T004	M003 + M005	Lead Content	%	0.001	0.05	< RL
T005	M008 + M010 + M012	Lead Content	%	0.001	0.05	< RL
T006	M009 + M011	Lead Content	%	0.001	0.05	< RL

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

Remark:

* Regulation on Lead:

Country	Legislation	Maximum Permissible Limit
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)
	Paragraph 7-10 of Entry 63 of Annex XVII, REACH Regulation (EC) No. 1907/2006	Articles supplied to the general public during normal or reasonably foreseeable conditions of use, be placed in the mouth by children 0.05% (by weight of the individual part) The limit shall not apply where it can be demonstrated that the rate of lead release from such an article or any such accessible part of an article, whether coated or uncoated, does not exceed 0,05 µg/cm² per hour (equivalent to 0,05 µg/g/h), and, for coated articles, that the coating is sufficient to ensure that this release rate is not exceeded for a period of at least two years of normal or reasonably foreseeable conditions of use of the article.

4.^Nonylphenol, Nonylphenolethoxylates

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

NPEO and OPEO:
Organic solvent extraction, LC-MS

Test Result:

Test No.	Material No.	Test Parameter	Unit	RL	Regulatory Requirement	Test Result
T001	M002	Nonylphenol (NP)	mg/kg	5	1000	< RL
		Nonylphenolethoxylates (NPEO)	mg/kg	20	1000	< RL
T002	M003 + M005	Nonylphenol (NP)	mg/kg	5	1000	< RL
		Nonylphenolethoxylates (NPEO)	mg/kg	20	1000	< RL
T003	M004 + M006	Nonylphenol (NP)	mg/kg	5	1000	< RL
		Nonylphenolethoxylates (NPEO)	mg/kg	20	1000	< RL
T004	M008	Nonylphenol (NP)	mg/kg	5	1000	< RL
		Nonylphenolethoxylates (NPEO)	mg/kg	20	1000	< RL
T005	M009 + M011	Nonylphenol (NP)	mg/kg	5	1000	< RL
		Nonylphenolethoxylates (NPEO)	mg/kg	20	1000	< RL
T006	M010 + M012	Nonylphenol (NP)	mg/kg	5	1000	< RL
		Nonylphenolethoxylates (NPEO)	mg/kg	20	1000	< RL

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

5.^Organotin compounds content

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

			Test No.	T001	T002	T003
			Material No.	M002 + M004 + M006	M003 + M005	M008 + M010 + M012
Test Parameter	Unit	RL	Regulatory Requirement	Result	Result	Result
TBT(Tributyltin) by weight of tin	%	0.01	--	< RL	< RL	< RL
TPT(Triphenyltin) by weight of tin	%	0.01	--	< RL	< RL	< RL
TOT(Trioctyltin) by weight of tin	%	0.01	--	< RL	< RL	< RL
TCyT(Tricyclohexyltin) by weight of tin	%	0.01	--	< RL	< RL	< RL
TPrT(Tripropyltin) by weight of tin	%	0.01	--	< RL	< RL	< RL
Sum of Tin of tri-substituted organotins	%	NA	0.1	<RL	<RL	<RL
DBT(Dibutyltin) by weight of tin	%	0.01	0.1	< RL	< RL	< RL
DOT(Dioctyltin) by weight of tin	%	0.01	0.1	< RL	< RL	< RL

			Test No.	T004
			Material No.	M009 + M011
Test Parameter	Unit	RL	Regulatory Requirement	Result
TBT(Tributyltin) by weight of tin	%	0.01	--	< RL
TPT(Triphenyltin) by weight of tin	%	0.01	--	< RL
TOT(Trioctyltin) by weight of tin	%	0.01	--	< RL
TCyT(Tricyclohexyltin) by weight of tin	%	0.01	--	< RL
TPrT(Tripropyltin) by weight of tin	%	0.01	--	< RL
Sum of Tin of tri-substituted organotins	%	NA	0.1	<RL
DBT(Dibutyltin) by weight of tin	%	0.01	0.1	< RL
DOT(Dioctyltin) by weight of tin	%	0.01	0.1	< RL

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

6.^Total Cadmium Content

Test Method: For plastic: EN 1122:2001 (method B)
For metal and other material: Acid digestion, analysised by AAS/ ICP-OES

Test Result:

Test No.	Material No.	Test Parameter	Unit	RL	Regulatory Requirement	Test Result
T001	M002 + M004 + M006	Cadmium	mg/kg	10	100	< RL
T002	M003 + M005	Cadmium	mg/kg	10	100	< RL
T003	M008 + M010 + M012	Cadmium	mg/kg	10	100	< RL
T004	M009 + M011	Cadmium	mg/kg	10	100	< RL

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

Remark:

* Regulations on Cadmium

		Maximum Permissible Limit				
EU	**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 Item 23 and its amendments (EC) No. 552/2009, (EU) No. 494/2011, (EU) No. 835/2012 and (EU) No. 217/2016.	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

7.^Flame Retardants

Test Method: Organic solvent extraction, analyzed by GCMS & LCMS

				Test No.	T001	T002
				Material No.:	M002	M003
Test Parameter	CAS No.	Unit	RL	Regulatory Requirement	Result	Result
Polybrominated biphenyls (PBB)	59536-65-1	mg/kg	5	5	< RL	< RL
Tris-aziridinyl phosphinoxide (TEPA)	545-55-1	mg/kg	5	5	< RL	< RL
Tris-(2,3-dibrompropyl) phosphate(TDBPP)	126-72-7	mg/kg	5	5	< RL	< RL
Octabromodiphenylether (OctaBDE)	32536-52-0	mg/kg	5	1000	< RL	< RL
Decabromodiphenylether (decaBDE)	1163-19-5	mg/kg	5	1000	< RL	< RL

				Test No.	T003	T004
				Material No.:	M004	M005
Test Parameter	CAS No.	Unit	RL	Regulatory Requirement	Result	Result
Polybrominated biphenyls (PBB)	59536-65-1	mg/kg	5	5	< RL	< RL
Tris-aziridinyl phosphinoxide (TEPA)	545-55-1	mg/kg	5	5	< RL	< RL
Tris-(2,3-dibrompropyl) phosphate(TDBPP)	126-72-7	mg/kg	5	5	< RL	< RL
Octabromodiphenylether (OctaBDE)	32536-52-0	mg/kg	5	1000	< RL	< RL
Decabromodiphenylether (decaBDE)	1163-19-5	mg/kg	5	1000	< RL	< RL

				Test No.	T005	T006
				Material No.:	M006	M008
Test Parameter	CAS No.	Unit	RL	Regulatory Requirement	Result	Result
Polybrominated biphenyls (PBB)	59536-65-1	mg/kg	5	5	< RL	< RL
Tris-aziridinyl phosphinoxide (TEPA)	545-55-1	mg/kg	5	5	< RL	< RL
Tris-(2,3-dibrompropyl) phosphate(TDBPP)	126-72-7	mg/kg	5	5	< RL	< RL
Octabromodiphenylether (OctaBDE)	32536-52-0	mg/kg	5	1000	< RL	< RL
Decabromodiphenylether (decaBDE)	1163-19-5	mg/kg	5	1000	< RL	< RL

				Test No.	T007	T008
				Material No.:	M009	M010
Test Parameter	CAS No.	Unit	RL	Regulatory Requirement	Result	Result
Polybrominated biphenyls (PBB)	59536-65-1	mg/kg	5	5	< RL	< RL
Tris-aziridinyl phosphinoxide (TEPA)	545-55-1	mg/kg	5	5	< RL	< RL
Tris-(2,3-dibrompropyl) phosphate(TDBPP)	126-72-7	mg/kg	5	5	< RL	< RL
Octabromodiphenylether (OctaBDE)	32536-52-0	mg/kg	5	1000	< RL	< RL
Decabromodiphenylether (decaBDE)	1163-19-5	mg/kg	5	1000	< RL	< RL

				Test No.	T009	T010
				Material No.:	M011	M012
Test Parameter	CAS No.	Unit	RL	Regulatory Requirement	Result	Result
Polybrominated biphenyls (PBB)	59536-65-1	mg/kg	5	5	< RL	< RL
Tris-aziridinyl phosphinoxide (TEPA)	545-55-1	mg/kg	5	5	< RL	< RL
Tris-(2,3-dibrompropyl) phosphate(TDBPP)	126-72-7	mg/kg	5	5	< RL	< RL
Octabromodiphenylether (OctaBDE)	32536-52-0	mg/kg	5	1000	< RL	< RL
Decabromodiphenylether (decaBDE)	1163-19-5	mg/kg	5	1000	< RL	< RL

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

Remark:

List of PBBs

List of PBDEs

List of PBBs	
1	Bromobiphenyl
2	Dibromobiphenyl
3	Tribromobiphenyl
4	Tetrabromobiphenyl
5	Pentabromobipheny
6	Hexabromobiphenyl
7	Heptabromobiphenyl
8	Octabromobiphenyl
9	Nonabromobiphenyl
10	Decabromobiphenyl

List of PBDEs	
1	Bromodiphenylether
2	Dibromodiphenyl ether
3	Tribromobiphenyl ether
4	Tetrabromobiphenyl ether
5	Pentabromobipheny ether
6	Hexabromobiphenyl ether
7	Heptabromobiphenyl ether
8	Octabromobiphenyl ether
9	Nonabromobiphenyl ether
10	Decabromobiphenyl ether

8. ^Banned azo dyes

Test Method: Method 1 - EN ISO 14362-1:2017 (Textiles) (Buffer extraction)
Method 2 - EN ISO 14362-1:2017 (Textiles) (Xylene extraction)
Method 3 - ISO 17234-1:2015 (Leather)
Method 4 - EN ISO 14362-3:2017 (Textile, 4-aminoazobenzene confirmation)
Method 5 - ISO 17234-2:2011 (Leather, 4-aminoazobenzene confirmation)

Test Results:

					Material No.	M003		M009	
					Test No.	T001-1	T001-2	T002-1	T002-2
					Method No.	Method 1	Method 2	Method 1	Method 2
					A22 Confirmation Method No.	--	--	--	--
ID	Test Parameter	CAS NO	Unit	RL	Regulatory Requirement	Result	Result	Result	Result
A1	4-Aminobiphenyl	92-67-1	mg/kg	5	30	< RL	< RL	< RL	< RL
A2	Benzidine	92-87-5	mg/kg	5	30	< RL	< RL	< RL	< RL
A3	4-Chloro-o-toluidine	95-69-2	mg/kg	5	30	< RL	< RL	< RL	< RL
A4	2-Naphthylamine	91-59-8	mg/kg	5	30	< RL	< RL	< RL	< RL
A5*	o-Aminoazotoluene	97-56-3	mg/kg	5	30	< RL	< RL	< RL	< RL
A6*	5-nitro-o-toluidine / 2-Amino-4-nitrotoluene	99-55-8	mg/kg	5	30	< RL	< RL	< RL	< RL
A7	4-Chloroaniline	106-47-8	mg/kg	5	30	< RL	< RL	< RL	< RL
A8	4-methoxy-m-phenylenediamine / 2,4-Diaminoanisole	615-05-4	mg/kg	5	30	< RL	< RL	< RL	< RL
A9	4,4'-Diaminodiphenylmethane	101-77-9	mg/kg	5	30	< RL	< RL	< RL	< RL
A10	3,3'-Dichlorobenzidine	91-94-1	mg/kg	5	30	< RL	< RL	< RL	< RL
A11	3,3'-Dimethoxybenzidine	119-90-4	mg/kg	5	30	< RL	< RL	< RL	< RL
A12	3,3'-Dimethylbenzidine	119-93-7	mg/kg	5	30	< RL	< RL	< RL	< RL
A13	4,4'-methylenedi-o-toluidine / 3,3'-Dimethyl-4,4'-diaminodiphenylmethane	838-88-0	mg/kg	5	30	< RL	< RL	< RL	< RL
A14	p-Cresidine	120-71-8	mg/kg	5	30	< RL	< RL	< RL	< RL
A15	4,4'-Methylene-bis-(2-chloroaniline)	101-14-4	mg/kg	5	30	< RL	< RL	< RL	< RL
A16	4,4'-Oxydianiline	101-80-4	mg/kg	5	30	< RL	< RL	< RL	< RL
A17	4,4'-Thiodianiline	139-65-1	mg/kg	5	30	< RL	< RL	< RL	< RL
A18	o-Toluidine	95-53-4	mg/kg	5	30	< RL	< RL	< RL	< RL
A19	4-methyl-m-phenylenediamine / 2,4-Toluylendiamine	95-80-7	mg/kg	5	30	< RL	< RL	< RL	< RL
A20	2,4,5-Trimethylaniline	137-17-7	mg/kg	5	30	< RL	< RL	< RL	< RL
A21	O-Anisidine	90-04-0	mg/kg	5	30	< RL	< RL	< RL	< RL
A22**	4-Aminoazobenzene	60-09-3	mg/kg	5	30	< RL	< RL	< RL	< RL

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

Remark:

* The CAS-number 97-56-3 (A5) and 99-55-8 (A6) are further reduced to CAS-number 95-53-4 (A18) and 95-80-7 (A19).

** Azo colorants that are able to form 4-aminoazobenzene (A22) CAS-number 60-09-3, generate under the condition of this method Aniline (CAS-number 62-53-3) and 1,4-phenylenediamine (CAS-number 106-50-3.)

*** Azo colorants that are able to form 4-aminoazobenzene (A22), is confirmed by EN ISO 14362-3:2017 / ISO 17234-2:2011.

**** Azo colorants are detected & quantified by GC/MS and confirmed by HPLC/DAD or HPLC/MSMS.

*1 Azo colorants A1 - A22 being tested according to REACH regulation (EC) No. 1907/2006 and amendment no. 552/2009 Annex XVII Item 43 (formerly known as 2002/61/EC)

9.^Phthalates content

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

Test Result:

			Test No.	T001	T002	T003
			Material No.	M002 + M004 + M006	M003 + M005	M008 + M010 + M012
Test Parameter	CAS NO	Unit	RL	Result	Result	Result
Diethylhexyl phthalate (DEHP)	117-81-7	%	0.005	< RL	< RL	< RL
Dibutyl phthalate (DBP)	84-74-2	%	0.005	< RL	< RL	< RL
Benzylbutyl phthalate (BBP)	85-68-7	%	0.005	< RL	< RL	< RL
Diisobutyl phthalate (DIBP)	84-69-5	%	0.005	< RL	< RL	< RL
Sum (DEHP+DBP+BBP+DIBP)	-	%	0.005	<RL	<RL	<RL
Diisononyl phthalate (DINP)	28553-12-0, 68515-48-0	%	0.005	< RL	< RL	< RL
Diisodecyl phthalate (DIDP)	26761-40-0, 68515-49-1	%	0.005	< RL	< RL	< RL
Di-n-octyl phthalate (DNOP)	117-84-0	%	0.005	< RL	< RL	< RL
Sum (DINP+ DIDP+ DNOP)	--	%	0.005	< RL	< RL	< RL
Conclusion: REACH regulation (EC) No. 1907/2006 and its amendment regulations on Annex XVII entries 51 and 52				Pass	Pass	Pass

			Test No.	T004
			Material No.	M009 + M011
Test Parameter	CAS NO	Unit	RL	Result
Diethylhexyl phthalate (DEHP)	117-81-7	%	0.005	< RL
Dibutyl phthalate (DBP)	84-74-2	%	0.005	< RL
Benzylbutyl phthalate (BBP)	85-68-7	%	0.005	< RL
Diisobutyl phthalate (DIBP)	84-69-5	%	0.005	< RL
Sum (DEHP+DBP+BBP+DIBP)	-	%	0.005	<RL
Diisononyl phthalate (DINP)	28553-12-0, 68515-48-0	%	0.005	< RL
Diisodecyl phthalate (DIDP)	26761-40-0, 68515-49-1	%	0.005	< RL
Di-n-octyl phthalate (DNOP)	117-84-0	%	0.005	< RL
Sum (DINP+ DIDP+ DNOP)	--	%	0.005	< RL
Conclusion: REACH regulation (EC) No. 1907/2006 and its amendment regulations on Annex XVII entries 51 and 52				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 and 52:

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.
Plasticised materials in children's toy and childcare articles which can be placed in the mouth by children:		
Di-n-octyl phthalate (DNOP) Diisodecyl phthalate (DIDP) Diisononyl phthalate (DINP)	%	0.1 (sum of the three phthalates)

Denote:
Examples of articles that are excluded from the restriction

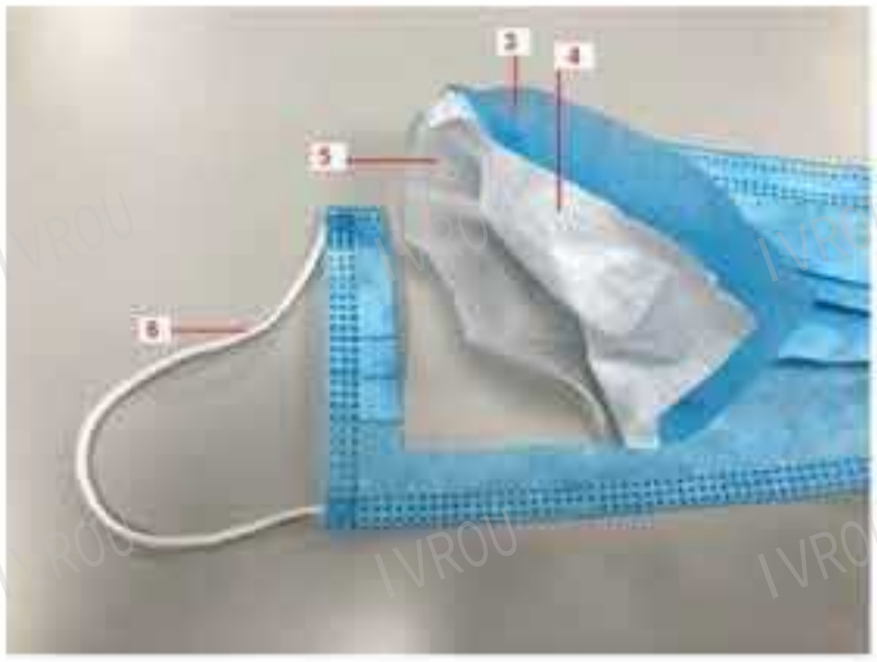
1) Articles exclusively for industrial / agricultural use / use in open air, provided that no plasticised material comes into contact with human mucous membranes or into prolonged contact with human skin (i.e. Continuous contact of more than 10 minutes duration or intermittent contact over a period of 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
7) Immediate packaging of medicinal products (Regulation (EC) No 726/2004, Directive 2001/82/EC or Directive 2001/83/EC)

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

^ This test is sub-contracted to a qualified laboratory of TÜV Rheinland Group.

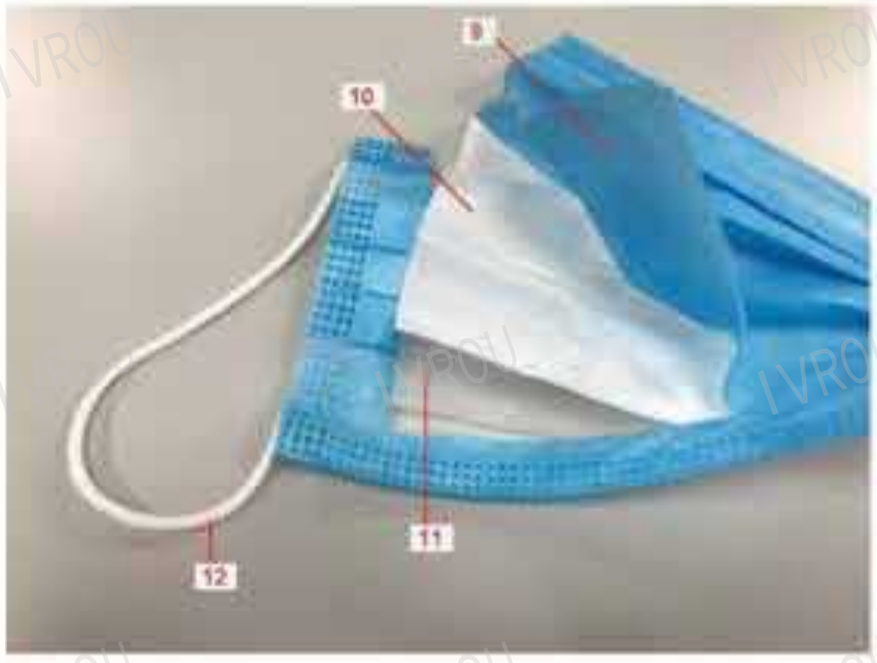
Sample Photos

Material No.1-2

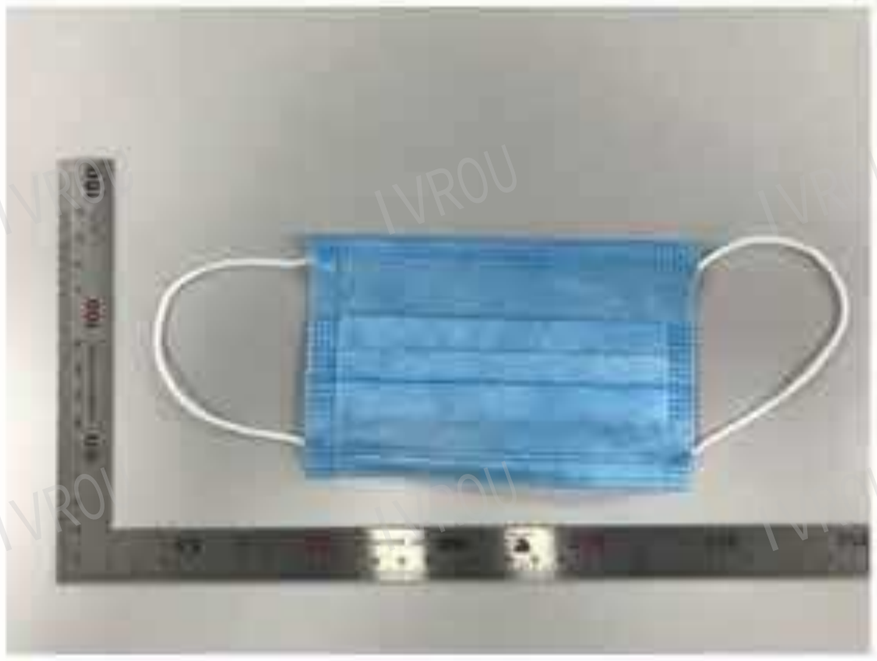


Material No.3-6

Material No.7-8



Material No.9-12



- 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 fundamental 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 one disclosure. Where the disclosing party fails to do so within the stipulated period, the receiving party shall not have 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 the 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 regulated 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, in the fullest extent permitted by applicable law, in the event of a breach of contractual obligations or tort, the liability 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 incurred thereof by TÜV Rheinland.

14. Data protection notice

TÜV Rheinland processes personal data of the client for the purpose of fulfilling the 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 concerned 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 cause, 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 pay 10% 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

SUBJECT	**Physical & Microbiological Test**
TEST LOCATION	**TÜV SÜD China** TÜV SÜD Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	**Guangzhou Shuter Technology Co.,Ltd**
CLIENT ADDRESS	No.882 South of Gongye Dadao, Haizhu District, Guangzhou City, Guangdong Province
TEST PERIOD	27-Mar-2020~08-Apr-2020

Prepared By

Bella Xu

(Bella Xu)
Report Drafter

Authorized By

Leo Liu

(Leo Liu)
Authorized Signatory

Note: (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested.(3) The test report shall not be reproduced except in full without the written approval of the laboratory.(4) Without the agreement of the laboratory , the client is not authorized to use the test results for unapproved propaganda.

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4, No.1999 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
Fax : +86 (21) 6037 6345
Email: food.chem@tuv-sud.cn
Webpage: www.tuv-sud.cn

Regional Head Office:
TÜV SÜD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

TEST REPORT

Sample Description	:	Disposable medical mask
Sample Quantity	:	60 pieces
Lot Number/Batch Code	:	/
Specification	:	/
Size	:	/
Style No	:	ST-KZ-01 Bar loop(nonsterile)
Type of Mask	:	Type IIR
Brand Name	:	/

Remark: The above information was provided by applicant.

Summary of Test Results

No.	Test Item	Test Standard	Judgement
1	Bacterial Filtration Efficiency (BFE) Test	EN 14683:2019+AC:2019(E) Annex B	Pass
2	Differential Pressure Test	EN 14683:2019+AC:2019(E) Annex C	Pass
3	Synthetic Blood Penetration Test	ISO 22609:2004	Pass
4	Microbial Cleanliness Test	EN 14683:2019+AC:2019(E) Annex D	Pass

Note: Pass = Meet customer requirements;
Fail = Fail customer requirements;
# = No comment;
N.D. = Not detected.

Photo of Samples

Restults

No.	Test Item	Test Result
1	Bacterial Filtration Efficiency (BFE) Test	Specimen 1#: 98.7% Specimen 2#: 99.0% Specimen 3#: 99.2% Specimen 4#: 98.8% Specimen 5#: 98.9%
2	Differential Pressure Test	25.1 Pa/cm^2
3	Synthetic Blood Penetration Test	Specimen 1#~13#: None seen
4	Microbial Cleanliness Test	Specimen 1#: 10 CFU/g Specimen 2#: 6 CFU/g Specimen 3#: 8 CFU/g Specimen 4#: 6 CFU/g Specimen 5#: 4 CFU/g

Bacterial Filtration Efficiency (BFE) Test

1. Purpose

For evaluating the bacterial filtration efficiency (BFE) of mask.

2. Sample description was given by client

Sample description : Disposable medical mask
Specification : /
Lot Number : /
Sample Receiving Date : 2020-03-27

3. Test Method

EN 14683:2019+AC:2019(E) Annex B

4. Apparatus and materials

4.1 *Staphylococcus aureus* ATCC 6538.
4.2 Peptone water.
4.3 Tryptic Soy Broth(TSB).
4.4 Tryptic Soy Agar(TSA).
4.5 Bacterial filtration efficiency test apparatus.
4.6 Six-stage viable particle Anderson sampler.
4.7 Flow meters.

5. Test specimen

5.1 As requested by client, take a total of 5 test specimens.
5.2 Prior to testing, condition all test specimens for a minimum of 4 h at (21±5)°C and (85±5)% relative humidity.

6. Procedure

6.1 Preparation of the bacterial challenge: Dilute the cultutre in peptone water to achieve a concentration of approximately 5×10^5 CFU/mL.
6.2 Adjust the flow rate through the Anderson sampler to 28.3 L/min.
6.3 Deliver the challenge to the nebulizer using a syringe pump. Purge tubing and nebulizer of air bubbles.
6.4 Perform a positive control run without a test specime to determine the number of viable aerosol particles being generated. The mean particle size (MPS) of the aerosol will also be calculated from the results of these positive control plates.
6.4.1 Initiate the aerosol challenge by turning on the air pressure and pump connected to the nebulizer. Immediaterly begin sampling the aerosol using the Anderson sampler.
6.4.2 Time the challenge suspension to be delivered to the nebulizer for 1 min.
6.4.3 Time the air pressure and Anderson sampler to run for 2 min.
6.4.4 At the conclusion of the positive control ran, remove plates from the Anderson sampler.
6.5 Place new agar plates into Anderson sampler and clamp the test specimen into the top of the Anderson sampler, with the inside of the specimen facing towards the bacterial challenge (test area: 77cm²).
6.6 Repeat the challenge procedure for each test specimen.
6.7 Repeat a positive control after completion of the sample set.
6.8 Perform a negative control run by collecting a 2 min sample of air from the aerosol chamber. No bacterial challenge should be pumped into the nebulizer during the collection of the negative control.
6.9 Incubate agar plates at (37±2)°C for (20 to 52) h.
6.10 Count each of the six-stage plates of the Anderson sampler.

7. Calculation

Total the count from each of the six plates for the test specimens and positive controls, as specified by the manufacture of Anderson sampler. The filtration efficiency percentages are calculated as follows:

$$BFE=(C-T)/C\times100$$

T is the total plate count for the test specimen.

C is the mean of the total plate counts for the two positive controls.

8. Test results*

Stage Number \ P Value	Positive Control (A)	Positive Control (B)	Negative Control	Specimen 1#	Specimen 2#	Specimen 3#	Specimen 4#	Specimen 5#
1	21	67	0	0	0	0	0	0
2	79	108	0	0	0	0	0	0
3	111	97	0	0	0	0	0	0
4	241	105	0	1	1	0	0	1
5	1288	1619	0	17	14	13	18	16
6	721	746	0	15	10	9	12	11
Total (*T*), CFU	2461	2742	<1	33	25	22	30	28
Average (C), CFU	$2.6x10^3 = (P_A+P_B) / 2$							
BFE ,%				98.7	99.0	99.2	98.8	98.9
Requirements	≥ 98							
Remarks	*P* is the value of corresponding corrected particle counts as specified by the manufacturer of the cascade impactor. *T* is the total of *P* value for the test specimen. *C* is the mean of the total of *P* value of the two positive controls.							

Differential pressure Test

1.Purpose

The purpose of the test was to measure the differential pressure of masks.

2.Sample description was given by client

Sample description : Disposable medical mask
Specification : /
Lot Number : /
Sample Receiving Date : 2020-03-27

3.Test Method

EN 14683:2019+AC:2019(E) Annex C

4. Apparatus and materials

Differential pressure testing instrument

5.Test specimen

5.1 Test specimen are complete masks or shall be cut from masks. Each specimen shall be able to provide 5 different circular test areas of 2.5 cm in diameter.
5.2 Prior to testing, condition all test specimens for a minimum of 4 h at (21±5) °C and (85±5)% relative humidity.

6. Procedure

6.1 Without a specimen in place, the holder is closed and the differential manometer is zeroed. The pump is started and the flow of air adjusted to 8 L/min.
6.2 The pretreated specimen is placed across the orifice (total area 4.9cm², test area diameter 25mm) and clamped into place so as to minimize air leaks.
6.3 Due to the presence of an alignment system the tested area of the specimen should be perfectly in line and across the flow of air.
6.4 The differential pressure is read directly.
6.5 The procedure described in steps 6.1-6.4 is carried out on 5 different areas of the mask and readings averaged.

Results:

Specimen	Test Results* (Pa/cm²)	Average (Pa/cm²)	Requirements	Judgement
1#	26.5	25.1	< 60	Pass
2#	24.6			
3#	23.2			
4#	26.3			
5#	25.0			

Synthetic Blood Penetration Test

1.Purpose

For evaluation of resistance of masks to penetration by a fixed volume of synthetic blood at a high velocity.

2.Sample description was given by client

Sample description	:	Disposable medical mask
Specification	:	/
Lot Number	:	/
Sample Receiving Date	:	2020-03-27

3.Test Method

ISO 22609:2004

4.Apparatus and materials

4.1 Synthetic blood.
4.2 Tensiometer.
4.3 Synthetic blood penetration test apparatus;
4.4 Targeting plate.
4.5 Air pressure source.
4.6 Ruler.
4.7 Balance.
4.8 Controlled temperature and humidity chamber.

5.Test specimen

5.1 As requested by client, take a total of 13 test specimens.
5.2 Prior to testing, condition all test specimens for a minimum of 4h at (21±5)°C and (85±5) % relative humidity.

6.Procedure

6.1 Prepare the synthetic blood (40~44 mN/m) for the test.
6.2 Determine the density of the synthetic blood.
6.3 Fill the reservoir with new synthetic blood.
6.4 Position the test specimen 30.5 cm (12 in.) from the exit of the canula.
6.5 Set the reservoir pressure to the approximate pressure.
6.6 Place the targeting plate approximately 1 cm away from the mask.
6.7 Set the valve timer to 0.5 s. Collect and weigh the amount of fluid delivered (before the targeting hole).

6.8 Set the valve timer to 1.5 s. Collect and weigh the amount of fluid delivered (before the targeting hole).

6.9 Calculate the difference in weight of the two spurts. For a test fluid with a density of 1.003, Table 1 gives the target difference in weight plus lower and upper limits for a velocity range within 2% of the target.

Table 1 Target weight difference

Fluid Pressure (mmHg)	Weight difference for 1s difference in spurt duration (g)		
	Min.	Target	Max.
120	3.002	3.063	3.124

6.10 Adjust the reservoir pressure and repeat steps 6.7 to 6.9 until the weight difference is within the target range.

6.11 Record the weight difference for the spurts exiting the nozzle.

6.12 Record the pressure in the reservoir.

6.13 Set the valve time to 0.5 s. Collect and weigh the amount of fluid passing through the targeting hole.

6.14 Set the valve time to 1.5 s. Collect and weigh the amount of fluid passing through the targeting hole.

6.15 The difference in weight between the 0.5 s and 1.5 s spurts through the targeting plate shall be within +2 % ~ -5 % of the difference in weight from the nozzle.

6.16 If the differential weight is less than 95 % of the weight difference exiting the nozzle, check the aim of the stream to make sure it is passing cleanly through the targeting hole.

6.17 If the differential weight is more than 102 % of the weight difference exiting the nozzle, repeat the weight measurements exiting the nozzle (steps 6.7 to 6.11).

6.18 For standard synthetic blood, the timer duration can be estimated using the formula:
(ρ is the density of the test fluid.) $t = 0.5 + (2\times \rho - g \text{ at } 0.5 \text{ s}) / (g \text{ at } 1.5 \text{ s} - g \text{ at } 0.5 \text{ s})$.

6.19 Record the timer setting to use as the starting point for subsequent testing.

6.20 Mount a test specimen on the specimen holding fixture. If the mask contains pleats, spread the pleats out when mounting the mask onto the fixture to present a single layer of material as the target area.

6.21 Squirt the synthetic blood onto the test specimen for the calculated time. Ensure that the synthetic blood hits the target area of mask.

6.22 Inspect the inside surface for synthetic blood penetration within 10 s of squirting the synthetic blood against the target area.

6.23 Report the results (none / penetration) for each test specimen at the test pressure.

Results:

Specimen	Test Results*	Requirements	Judgement
1#	None Seen	Pass Pressure at 16.0 kPa (120mmHg)	Pass
2#	None Seen		Pass
3#	None Seen		Pass
4#	None Seen		Pass
5#	None Seen		Pass
6#	None Seen		Pass
7#	None Seen		Pass
8#	None Seen		Pass
9#	None Seen		Pass
10#	None Seen		Pass
11#	None Seen		Pass
12#	None Seen		Pass
13#	None Seen		Pass

Microbial Cleanliness Test

1. Purpose

The purpose of the test was to measure microbial cleanliness of mask.

2. Sample description was given by client

Sample description : Disposable medical mask
Specification : /
Lot Number : /
Sample Receiving Date : 2020-03-27

3. Test Method

According to EN ISO 11737-1:2018 to determine the microbial cleanliness of mask material, and refer to the procedure as described in EN 14683:2019+AC:2019(E) Annex D

4. Apparatus and materials

4.1 Orbital shaker.
4.2 0.45 um filter.
4.3 Tryptic Soy Agar (TSA).
4.4 Sabouraud Dextrose Ager (SDA) with chloramphenicol.
4.5 Formula of Extraction Liquid: 1g/L peptone, 5g/L NaCl and 2g/L Tween 20.
4.6 Extraction apparatus.

5. Test specimen

5.1 As requested by client, take a total of 5 mask samples.
5.2 Mask samples for testing are provided in the original primary packaging.
5.3 Condition at (18 to 26)℃ and (45 to 65)% relative humidity during testing.

6. Procedure

6.1 Five test specimens are selected from the top, bottom and 3 randomly chosen marks.
6.2 The mask is aseptically removed from the packaging and placed in a sterile 500 mL bottle containing 300 mL of extraction liquid.
6.3 The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm.
6.4 After extracting, 100mL of the extraction liquid is filtered through a 0.45 um filter and laid down on a TSA plate for the total viable aerobic microbial count. Another 100 mL aliquot of the same extraction liquid is filtered in the same way and the filter plated on SDA for fungi enumeration.
6.5 The plates are incubated for 3 days at 30°C and 7 days at (20 to 25)°C for TSA and SDA plates respectively.
6.6 Calculate the colonies of each agar plate.

7. Calculation

For each test specimen calculate the microbial cleanliness as follows by counting the total colonies of the TSA and SDA plates.

Results*:

Specimen	Colonies of the TSA Plate	Colonies of the SDA Plate	Microbial Cleanliness, (CFU/g)	Requirements	Judgement
1#	9	1	10	According to EN ISO 11737-1:2018 the microbial cleanliness of the mask shall be ≤30 CFU/g tested.	Pass
2#	4	2	6		
3#	7	1	8		
4#	5	1	6		
5#	3	1	4		

Note:

1.*denotes this test was carried out by external laboratory assessed as competent.

2.This report is for internal use only such as internal scientific research ,education, quality control, product R&D.

-END OF THE TEST REPORT-

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IVROU®

Disposable Medical Mask

ST-KZ-01 EN14683:2019+TYPE IIR

Package

Single wrapped

130x253 mm

Inner Box

50 pcs/ box

225x125x85 mm

Carton

40 boxes/ carton

515x440x465 mm

G.W 8.65KG