

## **Medizinische Einweg OP – Maske Type IIR mit Spritzschutz, nicht steril, EN 14683: 2019 + AC: 2019, CE**



### Merkmale der medizinischen Einweg-OP-Maske, Typ IIR – EN 14683: 2019 + AC: 2019

- **Überprüft und zugelassen von Swissmedic als medizinische Typ IIR Maske, Swissmedic Abschlussverfügung Referenz Nr. 102641265**
- **Erfüllt die neueste Norm für Typ IIR Masken – EN 14683: 2019 + AC: 2019**
- **ISO 9001 / 14001 / 45001**
- **Bakterielle Filterleistung (BFE):  $\geq 98 \%$**
- **Empa Prüfbericht: Prüfbericht Nr. 5214025580-G von 22. September 2020**
- **Type IIR Splash Resistance nach ISO 22609: 2004**
- **Schützt Träger und Mitmenschen mittels hochwirksamen 3-Lagen-Vlies**
- **Hochqualitatives Vlies, hergestellt im melt-blown Verfahren**
- **Speziell spritzfeste Aussen-Beschichtung zum Schutz vor Blut und anderen Körperflüssigkeiten mit 30g / m<sup>2</sup> beschichtetem Vlies**
- **CE / EC-REP**
- **Testreport von SGS, ein weltweit führende Unternehmen in den Bereichen Prüfen, Testen, Verifizieren und Zertifizieren mit Sitz in Genf ( [www.sgs.ch](http://www.sgs.ch) )**
- **Zusätzlich SGS SVHC-Test vorhanden** (Substances of Very High Concern) bieten Unternehmen, Verbrauchern und Endverbrauchern die Gewissheit, dass getestete Produkte und Materialien keine schädlichen Mengen an Chemikalien enthalten, die für die menschliche Gesundheit und die Umwelt gefährlich sind
- **Permanente, rollende Qualitätsüberwachung mittels Q-Tests vom Importeur bei SGS durchgeführt**
- **4-sprachige Verpackung und User-Manual**
- **Amfori BSCI zertifizierter** von BVQ / Weltklasse-Tools zur Steuerung der sozialen und ökologischen Leistung der ganzen Lieferketten & Herstellung [www.amfori.org](http://www.amfori.org)

## Technische Daten

- Überprüft und zugelassen von Swissmedic als medizinische Typ IIR Maske, Swissmedic Abschlussverfügung Referenz Nr. 102641265
- Empa Prüfbericht: Prüfbericht Nr. 5214025580-G von 22.September 2020
- EN 14683: 2019 + AC: 2019 Type IIR Einweg-Schutzmasken mit Ohrengummis
- Nach der Swiss National COVID-19 Science Task Force Empfehlungen für Community Masken - **BFE > 70% für 1µm Partikel**
- Type IIR: Spritzfeste Schicht zum Schutz vor Blut und anderen Körperflüssigkeiten
- nicht steril, für Einmalgebrauch
- Bakterielle Filterleistung (Bacteria Filter Efficiency - BFE):  $\geq 98\%$  nach EN 14683: 2019 + AC: 2019
- ISO 9001 / 14001 / 45001 und CE EC-REP
- Faltausführung mit elastischen Ohrschlingen
- Wirksamer 3-Lagen-Typ IIR Schutz aus hochqualitativem Vlies
  - 1. Lage: Auslaufsicherer Vliesstoff (hell-blau, 30g / m<sup>2</sup>)
  - 2. Lage: Hochdichtes schmelzgeblasenes Filtergewebe
  - 3. Lage: Vliesschicht für direkten Hautkontakt
- Integrierter biegbarer, versiegelter Nasenbügel, Latex und glasfaserfrei
- Hoher Tragkomfort, kann auch von Brillenträgern getragen werden
- Die leichte Ohrbügelmaske lässt sich einfach aufsetzen und entfernen
- Sie ist bequem und es ist leicht zu atmen
- Maskengrösse: 17.5 x 9.5 cm
- Verpackungseinheit: 50er-Packung per Box / 2'500 Box per Karton / 40'000 Stk. per Palette, Verpackung mit EAN Bar Code, Qualitäts-Bestätigung mit Lot-Nr. in Box
- 2'500 Stk. / Karton, Brutto-Gewicht 12.2kg, Grösse 55\*41\*40 cm

Was / What	Details	Bemerkung / Remarks
China Ministry of Commerce White List producer	Ja	CE
CE Certificate	Lotus BV NL as EU Representative	EC REP
Test report by	SGS	Swiss certification institution
Applied standard for SGS	EN 14683:2019+AC2019	Type IIR
Test report by	Empa Report Nr. G521402280-G from 22 September 2020	Empa überprüfte, ob die Maske die Empfehlungen der Swiss National COVID-19 Science Task Force erfüllt hat (Punkt 6 Prüfbericht)". (Empa hat die Masken geprüft aber nicht die Produktion zertifiziert, was bedeuten würde, dass alle Masken zertifiziert und geprüft wurden. Siehe Prüfbericht Punkt 8)
Applied standard for Empa	Empfehlungen der Swiss National COVID-19 Science Task Force	Swiss recommendation Schweizer Empfehlung
Factory ISO certificate	9001 / 14001 / 45001	
Product classification	medical use	
Sterile / Non Sterile	non sterile	
Packing	50 pcs / box 2500 pcs / ctn 11,1 kg / ctn	

## Für EN 14683: 2019 + AC: 2019

### Technisches KNOW-HOW

Prüfung	Typ I	Typ I R	Typ II	Typ II R
Bakterielle Filterleistung	≥95 %	≥95 %	≥98 %	≥98 %
Druckdifferenz Pa	< 29,4	< 49,0	< 29,4	< 49,0
Druck des Spritzwiderstandes mm Hg	entfällt	≥120	entfällt	≥120
Widerstandsfähig gegen Flüssigkeitsspritzer		ja		ja

Typ II ist also besser als Typ I und R bedeutet höhere Beständigkeit gegen Flüssigkeiten und Aerosole.

Typ I (>95%) oder Typ II (>98%) deklariert die bakterielle Filterleistung (bei Partikeln von 3 Mikrometer), was nichts mit Aerosolen zu tun hat.

Der Zusatz "R" deklariert einen ausreichenden Spritzschutz

Die Hauptfunktion von medizinische Gesichtsmasken ist der Schutz des Patienten / des Umfelds (source control), wobei natürlich auch von einem Trägerschutz ausgegangen werden kann (Prävention).

### Einweg Medical Type IIR mit Spritzschutz

#### **Medizinische Gesichtsmasken des Typ IIR schützen den Träger und andere Personen.**

Sie reduzieren einen Kontakt des Trägers mit grossen, ausgeworfenen Teilchen einer erkrankten Person (z.B. Speichel, Schleim);

Sie schützt bedingt ausserdem den Träger vor Blut und / oder anderen Körperflüssigkeiten des Patienten oder aus dem Arbeitsumfeld.

Masken des Typs IIR – EN 14683: 2019 + AC: 2019 sind geeignet für Situationen, in denen die/der medizinische Mitarbeiter das Risiko eines Kontakts mit Blut und/oder anderen Körperflüssigkeiten des Patienten oder aus dem Arbeitsumfeld besteht oder für den privaten Gebrauch **zum bedingten Eigenschutz und Schutz der Mitmenschen.**

**SGS -Test EN 14683: 2019 + AC: 2019 und ISO 22609:2004 (mit Spritzschutz)**

**Test Report**

**SL52025269923601TX**

**Date: July 01, 2020**

中国认可  
国际互认  
检测  
TESTING  
CNAS L0599

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SHANDONG POP JEANS INTELLIGENT MANUFACTURING CO.,LTD  
NO.188, GENGJIAO ROAD, HUANTAI, ZIBO, SHANDONG, CHINA

The following sample(s) was/were submitted and identified on behalf of the client as:

- Sample Description : (A) SINGLE-USE MEDICAL FACE MASK (ASPOP Brand)
- Style No. : SN20200003 / SN2020000301 / SN2020000307
- Composition : (A) Polypropylene
- Sample Color : (A) blue
- Manufacturer : SHANDONG POP JEANS INTELLIGENT MANUFACTURING CO.,LTD
- Lot No./Batch No. : Not provided
- Test Performed : Selected test(s) as requested by applicant
- Sample Receiving Date : Jun 08, 2020
- Testing Period : Jun 08, 2020 - Jul 01, 2020
- Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Signed for and on behalf of  
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)

Dongjing Liu / Hailian Xuan (Authorized Signatory)



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Test Result

**EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods**

**Clause 5.2 Performance Requirement**

**Clause 5.2.2 Bacterial filtration efficiency (BFE)**

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

Sample: A  
 Conditioning Parameters : Minimum of 4 hours at 21±5°C and 85±5% R.H.  
 Dimensions of test specimen : ~170 mm x 160 mm  
 Test Area : ~60 cm<sup>2</sup>  
 Test Side : Inside  
 Flow Rate : 28.3 l/min  
 Positive Control Average : 2312 CFU  
 Negative Monitor Count : < 1 CFU

(BFE), %	1#	2#	3#	4#	5#
	99.9	99.9	99.9	99.9	99.9

Remark: Performance Requirement: Type I ≥95%, Type II ≥98%, Type IIR ≥98%

**Clause 5.2.3 Breathability**

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

Sample: A  
 Test number and location : 5 random areas for each specimen (face mask)  
 Conditioning Parameters : Minimum of 4 hours at 21±5°C and 85±5% R.H.  
 Test Area : 4.9 cm<sup>2</sup>  
 Flow Rate : 8 l/min

Differential pressure ΔP (Pa/cm <sup>2</sup> )	1#	2#	3#	4#	5#
	48	46	47	48	49

Remark: Performance Requirement: Type I <40 Pa/cm<sup>2</sup>, Type II <40 Pa/cm<sup>2</sup>, Type IIR <60 Pa/cm<sup>2</sup>

**Clause 5.2.4 Splash Resistance**

(ISO 22809 :2004, Pressure 16.0 kPa)

Penetration on inside surface							
1#	2#	3#	4#	5#	6#	7#	8#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
9#	10#	11#	12#	13#	14#	15#	16#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
17#	18#	19#	20#	21#	22#	23#	24#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
25#	26#	27#	28#	29#	30#	31#	32#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Number of Pass:				32			
Overall result:				Acceptable			



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Remark:

- 1) Performance Requirement Type I: N/A, Type II: N/A, Type IIR:  $\geq 16.0\text{kPa}$
- 2) Distance of the medical face mask target area surface to the tip of cannula is  $300\pm 10\text{mm}$ .
- 3) Condition and Test temperature  $(21\pm 5)^\circ\text{C}$ , relative humidity  $(85\pm 10)\%$
- 4) An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show pass results

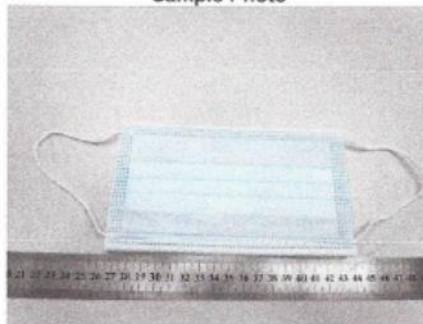
**Clause 5.2.5 Microbial Cleanliness**

(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

Sample Number	Mask Weight(g)	Total Bioburden, (cfu/mask)	Total Bioburden, (cfu/g)
1#	3.08	3	0.97
2#	3.10	<3	<0.97
3#	3.18	3	0.94
4#	3.11	3	0.96
5#	3.12	3	0.96

Remark: Performance Requirement: Type I  $\leq 30\text{ CFU/g}$ , Type II  $\leq 30\text{ CFU/g}$ , Type IIR  $\leq 30\text{ CFU/g}$

Sample Photo



The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

\*\*\*End of Report\*\*\*



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**SGS SVHC-Test (Substances of Very High Concern) / Test bezüglich schädliche Mengen an Chemikalien**



**Test Report**                      **SL22002253220301TX**                      **Date: May 20, 2020**                      **Page 1 of 16**  
 SHANDONG POP JEANS INTELLIGENT MANUFACTURING CO.,LTD  
 188 GENGJIAO ROAD, HUANTAI COUNTY, ZIBO CITY, SHANDONG PROVINCE

The following sample(s) was/were submitted and identified on behalf of the client as:  
 Sample Description : (A) single-use medical face mask (non-sterile) in blue

Sample Receiving Date : May 14, 2020  
 Testing Period : May 14, 2020 - May 20, 2020  
 Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Test Performed : Selected test(s) as requested by applicant

**Summary :**

According to the ruling of the Court of Justice of the European Union on the definition of an article under REACH, and the specified scope and evaluation screening, the test results of SVHC are  $\leq 0.1\%$  (w/w) in the articles of the submitted sample. **PASS**

Signed for and on behalf of  
 SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.

York Yao (Account Executive)



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**SVHC**

Test Sample :

Sample Description :

Specimen No.	SGS Sample ID	Description
SN1	TAO20-018009.001	non metal group
SN2	TAO20-018009.002	metal group

SGS Sample ID	Photo No.	Material Description
001	P1	Blue fabric
001	P2	White fabric
001	P3	White fabric
001	P4	White fabric
001	P5	White plastic
002	P6	Silvery metal

Test Result

Test Result: (Substances in the Candidate List of SVHC)

Batch	Substance Name	CAS No.	001 Concentration (%)	RL (%)
-	All tested SVHC in candidate list	-	ND	-

Test Result: (Substances in the Consultation List of potential SVHC)

Batch	Substance Name	CAS No.	001 Concentration (%)	RL (%)
-	All tested SVHC in consultation list	-	ND	-

Test Result: (Substances in the Candidate List of SVHC)

Batch	Substance Name	CAS No.	002 Concentration (%)	RL (%)
-	All tested SVHC in candidate list	-	ND	-



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**Notes :**

1. The table above only shows detected SVHC, and SVHC that below RL are not reported.  
Please refer to Appendix for the full list of tested SVHC.
2. RL = Reporting Limit (Test data will be shown if it ≥ RL. RL is not regulatory limit.)  
ND = Not detected (lower than RL), ND is denoted on the SVHC substance.
3. Δ CAS No. of diastereoisomers identified (α-HBCDD, β-HBCDD, γ-HBCDD): 134237-50-6, 134237-51-7, 134237-52-8  
☆ CAS No. of Hexahydromethylphthalic anhydride, Hexahydro-4-methylphthalic anhydride, Hexahydro-1-methylphthalic anhydride, Hexahydro-3-methylphthalic anhydride: 25550-51-0, 19438-60-9, 48122-14-1, 57110-29-9; EC No. of those: 247-094-1, 243-072-0, 256-356-4, 260-566-1.
4. \* The test result is based on the calculation of selected element(s) and to the worst-case scenario.  
\*\* The test result is based on the calculation of selected marker(s) and to the worst-case scenario.  
For detail information, please refer to the SGS REACH website: <http://www.sgs.com/en/Consumer-Goods-Retail/Toys-and-Juvenile-Products/Toys/REACH/Management-of-SVHC.aspx>  
Calculated concentration of boric compounds are based on the total boron for liquid, powder and paste samples and water extractive boron for other samples by ICP-OES.  
RL = 0.01% is evaluated for element (i.e. cobalt, arsenic, lead, chromium (VI), aluminum, zirconium, boron, strontium, zinc, antimony, titanium, barium and cadmium respectively), except molybdenum RL=0.001%, boron RL=0.005% (only for Lead bis(tetrafluoroborate), chromium (VI) RL=0.005% (only for Pentazinc chromate octahydroxide).
5. § The substance is proposed for the identification as SVHC only where it contains Michler's ketone (CAS Number: 90-94-8) or Michler's base (CAS Number: 101-61-1) ≥0.1% (w/w).
6. Composite test has been performed in equal proportion for the components/material per client requested. And the result is calculated using the minimum sample weight.
7. In consideration of the analysis requirement and the limit of sample volume, the screening test for the article is based on components / material enough to test.
8. / = Substances in the Consultation List of SVHC.



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**Appendix**
**Full list of tested SVHC:**

Batch	No.	Substance Name	CAS No.	RL (%)
I	1	4,4' -Diaminodiphenylmethane(MDA)	101-77-9	0.100
I	2	5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	81-15-2	0.100
I	3	Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	85535-84-8	0.100
I	4	Anthracene	120-12-7	0.100
I	5	Benzyl butyl phthalate (BBP)	85-68-7	0.100
I	6	Bis (2-ethylhexyl)phthalate (DEHP)	117-81-7	0.100
I	7	Bis(tributyltin)oxide (TBTO)	56-35-9	0.100
I	8	Cobalt dichloride*	7646-79-9	0.010
I	9	Diarsenic pentaoxide*	1303-28-2	0.010
I	10	Diarsenic trioxide*	1327-53-3	0.010
I	11	Dibutyl phthalate (DBP)	84-74-2	0.100
I	12	Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified ( $\alpha$ -HBCDD, $\beta$ -HBCDD, $\gamma$ -HBCDD) $\Delta$	25637-99-4, 3194-55-6	0.100
I	13	Lead hydrogen arsenate*	7784-40-9	0.010
I	14	Sodium dichromate*	7789-12-0, 10588-01-9	0.010
I	15	Triethyl arsenate*	15606-95-8	0.010
II	16	2,4-Dinitrotoluene	121-14-2	0.100
II	17	Acrylamide	79-06-1	0.100
II	18	Anthracene oil**	90640-80-5	0.100
II	19	Anthracene oil, anthracene paste**	90640-81-6	0.100
II	20	Anthracene oil, anthracene paste, anthracene fraction**	91995-15-2	0.100



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**Appendix**
**Full list of tested SVHC:**

Batch	No.	Substance Name	CAS No.	RL (%)
II	21	Anthracene oil, anthracene paste, distr. lights**	91995-17-4	0.100
II	22	Anthracene oil, anthracene-low**	90640-82-7	0.100
II	23	Diisobutyl phthalate	84-69-5	0.100
II	24	Lead chromate molybdate sulphate red (C.I. Pigment Red 104)*	12656-85-8	0.010
II	25	Lead chromate*	7758-97-6	0.010
II	26	Lead sulfochromate yellow (C.I. Pigment Yellow 34)*	1344-37-2	0.010
II	27	Pitch, coal tar, high temp.**	65996-93-2	0.100
II	28	Tris(2-chloroethyl)phosphate	115-96-8	0.100
III	29	Ammonium dichromate*	7789-09-5	0.010
III	30	Boric acid*	10043-35-3, 11113-50-1	0.010
III	31	Disodium tetraborate, anhydrous*	1303-96-4, 1330-43-4, 12179-04-3	0.010
III	32	Potassium chromate*	7789-00-6	0.010
III	33	Potassium dichromate*	7778-50-9	0.010
III	34	Sodium chromate*	7775-11-3	0.010
III	35	Tetraboron disodium heptaoxide, hydrate*	12267-73-1	0.010
III	36	Trichloroethylene	79-01-6	0.100
IV	37	2-Ethoxyethanol	110-80-5	0.100
IV	38	2-Methoxyethanol	109-86-4	0.100
IV	39	Chromic acid, Oligomers of chromic acid and dichromic acid, Dichromic acid*	7738-94-5 - 13530-68-2	0.010



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**Test Report**
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**Appendix**
**Full list of tested SVHC:**

Batch	No.	Substance Name	CAS No.	RL (%)
IV	40	Chromium trioxide*	1333-82-0	0.010
IV	41	Cobalt(II) carbonate*	513-79-1	0.010
IV	42	Cobalt(II) diacetate*	71-48-7	0.010
IV	43	Cobalt(II) dinitrate*	10141-05-6	0.010
IV	44	Cobalt(II) sulphate*	10124-43-3	0.010
V	45	1,2,3-trichloropropane	96-18-4	0.100
V	46	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	71888-89-6	0.100
V	47	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	68515-42-4	0.100
V	48	1-methyl-2-pyrrolidone	872-50-4	0.100
V	49	2-ethoxyethyl acetate	111-15-9	0.100
V	50	Hydrazine	7803-57-8, 302-01-2	0.100
V	51	Strontium chromate*	7789-06-2	0.010
VI	52	1,2-Dichloroethane	107-06-2	0.100
VI	53	2,2'-dichloro-4,4'-methylenedianiline	101-14-4	0.100
VI	54	2-Methoxyaniline; o-Anisidine	90-04-0	0.100
VI	55	4-(1,1,3,3-tetramethylbutyl)phenol	140-66-9	0.100
VI	56	Aluminosilicate Refractory Ceramic Fibres *	650-017-00-8 (Index no.)	0.010
VI	57	Arsenic acid*	7778-39-4	0.010
VI	58	Bis(2-methoxyethyl) ether	111-96-6	0.100
VI	59	Bis(2-methoxyethyl) phthalate	117-82-8	0.100



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**Full list of tested SVHC:**

Batch	No.	Substance Name	CAS No.	RL (%)
VI	60	Calcium arsenate*	7778-44-1	0.010
VI	61	Dichromium tris(chromate) *	24613-89-6	0.010
VI	62	Formaldehyde, oligomeric reaction products with aniline	25214-70-4	0.100
VI	63	Lead diazide, Lead azide*	13424-46-9	0.010
VI	64	Lead dipicrate*	6477-64-1	0.010
VI	65	Lead styphnate*	15245-44-0	0.010
VI	66	N,N-dimethylacetamide	127-19-5	0.100
VI	67	Pentazinc chromate octahydroxide*	49663-84-5	0.010
VI	68	Phenolphthalein	77-09-8	0.100
VI	69	Potassium hydroxyoctaoxidizincatedichromate*	11103-86-9	0.010
VI	70	Trilead diarsenate*	3687-31-8	0.010
VI	71	Zirconia Aluminosilicate Refractory Ceramic Fibres*	650-017-00-8 (Index no.)	0.010
VII	72	[4-[[4-anilino-1-naphthyl]]4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride (C.I. Basic Blue 26)§	2580-56-5	0.100
VII	73	[4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylamm onium chloride (C.I. Basic Violet 3)§	548-62-9	0.100
VII	74	1,2-bis(2-methoxyethoxy)ethane (TEGDME; triglyme)	112-49-2	0.100
VII	75	1,2-dimethoxyethane; ethylene glycol dimethyl ether (EGDME)	110-71-4	0.100
VII	76	4,4'-bis(dimethylamino) benzophenone (Michler's Ketone)	90-94-8	0.100
VII	77	4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol§	561-41-1	0.100



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**Appendix**

**Full list of tested SVHC:**

Batch	No.	Substance Name	CAS No.	RL (%)
VII	78	Diboron trioxide*	1303-86-2	0.010
VII	79	Formamide	75-12-7	0.100
VII	80	Lead(II) bis(methanesulfonate)*	17570-76-2	0.010
VII	81	N,N,N',N'-tetramethyl-4,4'-methylenedianiline (Michler's base)	101-61-1	0.100
VII	82	TGIC (1,3,5-tris(oxiranylmethyl)-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione)	2451-62-9	0.100
VII	83	α,α-Bis[4-(dimethylamino)phenyl]-4 (phenylamino)naphthalene-1-methanol (C.I. Solvent Blue 4) §	6786-83-0	0.100
VII	84	β-TGIC (1,3,5-tris[(2S and 2R)-2,3-epoxypropyl]-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione)	59653-74-6	0.100
VIII	85	[Phthalato(2-)]dioxotrilead*	69011-06-9	0.010
VIII	86	1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	84777-06-0	0.100
VIII	87	1,2-Diethoxyethane	629-14-1	0.100
VIII	88	1-Bromopropane	106-94-5	0.100
VIII	89	3-Ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine	143860-04-2	0.100
VIII	90	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated	-	0.100
VIII	91	4,4'-Methylenedi-o-toluidine	838-88-0	0.100
VIII	92	4,4'-Oxydianiline and its salts	101-80-4	0.100
VIII	93	4-Aminoazobenzene	60-09-3	0.100
VIII	94	4-Methyl-m-phenylenediamine	95-80-7	0.100
VIII	95	4-Nonylphenol, branched and linear	-	0.100
VIII	96	6-Methoxy-m-toluidine	120-71-8	0.100



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**Appendix**
**Full list of tested SVHC:**

Batch	No.	Substance Name	CAS No.	RL (%)
VIII	97	Acetic acid, lead salt, basic*	51404-69-4	0.010
VIII	98	Biphenyl-4-ylamine	92-67-1	0.100
VIII	99	Bis(pentabromophenyl) ether (DecaBDE)	1163-19-5	0.100
VIII	100	Cyclohexane-1,2-dicarboxylic anhydride, cis-cyclohexane-1,2-dicarboxylic anhydride, trans-cyclohexane-1,2-dicarboxylic anhydride	85-42-7, 13149-00-3, 14166-21-3	0.100
VIII	101	Diazene-1,2-dicarboxamide (C,C'-azodi(formamide))	123-77-3	0.100
VIII	102	Dibutyltin dichloride (DBTC)	683-18-1	0.100
VIII	103	Diethyl sulphate	64-67-5	0.100
VIII	104	Diisopentylphthalate	605-50-5	0.100
VIII	105	Dimethyl sulphate	77-78-1	0.100
VIII	106	Dinoseb	88-85-7	0.100
VIII	107	Dioxobis(stearato)trilead*	12578-12-0	0.010
VIII	108	Fatty acids, C16-18, lead salts*	91031-62-8	0.010
VIII	109	Furan	110-00-9	0.100
VIII	110	Henicosfluoroundecanoic acid	2058-94-8	0.100
VIII	111	Heptacosfluorotetradecanoic acid	376-06-7	0.100
VIII	112	Hexahydromethylphthalic anhydride, Hexahydro-4-methylphthalic anhydride, Hexahydro-1-methylphthalic anhydride, Hexahydro-3-methylphthalic anhydride	☆	0.100
VIII	113	Lead bis(tetrafluoroborate)*	13814-96-5	0.010
VIII	114	Lead cyanamidate*	20837-86-9	0.010
VIII	115	Lead dinitrate*	10099-74-8	0.010



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Appendix

Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
VIII	116	Lead monoxide*	1317-36-8	0.010
VIII	117	Lead oxide sulfate*	12036-76-9	0.010
VIII	118	Lead tetroxide (orange lead)*	1314-41-6	0.010
VIII	119	Lead titanium trioxide*	12060-00-3	0.010
VIII	120	Lead titanium zirconium oxide*	12626-81-2	0.010
VIII	121	Methoxyacetic acid	625-45-6	0.100
VIII	122	Methyloxirane (Propylene oxide)	75-56-9	0.100
VIII	123	N,N-dimethylformamide	68-12-2	0.100
VIII	124	N-Methylacetamide	79-16-3	0.100
VIII	125	N-Pentyl-isopentylphthalate	776297-69-9	0.100
VIII	126	o-Aminoazotoluene	97-56-3	0.100
VIII	127	o-Toluidine	95-53-4	0.100
VIII	128	Pentacosafluorotridecanoic acid	72629-94-8	0.100
VIII	129	Pentalead tetraoxide sulphate*	12065-90-6	0.010
VIII	130	Pyrochlore, antimony lead yellow*	8012-00-8	0.010
VIII	131	Silicic acid, barium salt, lead-doped*	68784-75-8	0.010
VIII	132	Silicic acid, lead salt*	11120-22-2	0.010
VIII	133	Sulfurous acid, lead salt, dibasic*	62229-08-7	0.010
VIII	134	Tetraethyllead*	78-00-2	0.010
VIII	135	Tetralead trioxide sulphate*	12202-17-4	0.010
VIII	136	Tricosfluorododecanoic acid	307-55-1	0.100



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**Full list of tested SVHC:**

Batch	No.	Substance Name	CAS No.	RL (%)
VIII	137	Trilead bis(carbonate)dihydroxide (basic lead carbonate)*	1319-46-6	0.010
VIII	138	Trilead dioxide phosphonate*	12141-20-7	0.010
IX	139	4-Nonylphenol, branched and linear, ethoxylated	-	0.100
IX	140	Ammonium pentadecafluorooctanoate (APFO)**	3825-26-1	0.100
IX	141	Cadmium oxide*	1306-19-0	0.010
IX	142	Cadmium*	7440-43-9	0.010
IX	143	Dipentyl phthalate (DPP)	131-18-0	0.100
IX	144	Pentadecafluorooctanoic acid (PFOA)	335-67-1	0.100
X	145	Cadmium sulphide*	1306-23-6	0.010
X	146	Dihexyl phthalate	84-75-3	0.100
X	147	Disodium 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis(4-aminonaphthalene-1-sulphonate) (C.I. Direct Red 28)	573-58-0	0.100
X	148	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	0.100
X	149	Imidazolidine-2-thione; 2-imidazoline-2-thiol	96-45-7	0.100
X	150	Lead di(acetate)*	301-04-2	0.010
X	151	Trixylyl phosphate	25155-23-1	0.100
XI	152	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	68515-50-4	0.100
XI	153	Cadmium chloride*	10108-64-2	0.010
XI	154	Sodium perborate; perboric acid, sodium salt*	-	0.010



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**Test Report**      **SL22002253220301TX**      **Date: May 20, 2020**      **Page 12 of 16**
**Appendix**
**Full list of tested SVHC:**

Batch	No.	Substance Name	CAS No.	RL (%)
XI	155	Sodium peroxometaborate*	7632-04-4	0.010
XII	156	2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)	25973-55-1	0.100
XII	157	2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)	3846-71-7	0.100
XII	158	2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)	15571-58-1	0.100
XII	159	Cadmium fluoride*	7790-79-6	0.010
XII	160	Cadmium sulphate*	10124-36-4, 31119-53-6	0.010
XII	161	Reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate & 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 & MOTE)	-	0.100
XIII	162	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	68515-51-5, 68648-93-1	0.100
XIII	163	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 isomers of [1] and [2] or any combination thereof]	-	0.100
XIV	164	1,3-propanesultone	1120-71-4	0.100
XIV	165	2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327)	3864-99-1	0.100
XIV	166	2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350)	36437-37-3	0.100
XIV	167	Nitrobenzene	98-95-3	0.100



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Test Report **SL22002253220301TX** Date: **May 20, 2020** Page **13 of 16**

**Appendix**

**Full list of tested SVHC:**

Batch	No.	Substance Name	CAS No.	RL (%)
XIV	168	Perfluorononan-1-oic-acid and its sodium and ammonium salts	375-95-1, 21049-39-8, 4149-60-4	0.100
XV	169	Benzo[def]chrysene (Benzo[a]pyrene)	50-32-8	0.100
XVI	170	4,4'-isopropylidenediphenol (bisphenol A)	80-05-7	0.100
XVI	171	4-Heptylphenol, branched and linear	-	0.100
XVI	172	Nonadecafluorodecanoic acid (PFDA) and its sodium and ammonium salts	3108-42-7, 335-76-2, 3830-45-3	0.100
XVI	173	p-(1,1-dimethylpropyl)phenol	80-46-6	0.100
XVII	174	Perfluorohexane-1-sulphonic acid and its salts	-	0.100
XVIII	175	1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo[12.2.1.1.6,9.02,13.05,10]octadeca-7,15-diene ("Dechlorane Plus™") [covering any of its individual anti- and syn-isomers or any combination thereof]	-	0.100
XVIII	176	Benzo[a]anthracene	56-55-3, 1718-53-2	0.100
XVIII	177	Cadmium nitrate*	10022-68-1, 10325-94-7	0.010
XVIII	178	Cadmium carbonate*	513-78-0	0.010
XVIII	179	Cadmium hydroxide*	21041-95-2	0.010
XVIII	180	Chrysene	218-01-9, 1719-03-5	0.100
XVIII	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]	-	0.100
XIX	182	Benzene-1,2,4-tricarboxylic acid 1,2-anhydride (trimellitic anhydride) (TMA)	552-30-7	0.100
XIX	183	Benzo[ghi]perylene	191-24-2	0.100



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Test Report SL22002253220301TX Date: May 20, 2020 Page 14 of 16

Appendix

Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
XIX	184	Decamethylcyclotrasiloxane (D5)	541-02-6	0.100
XIX	185	Dicyclohexyl phthalate (DCHP)	84-61-7	0.100
XIX	186	Disodium octaborate*	12008-41-2	0.010
XIX	187	Dodecamethylcyclotrasiloxane (D6)	540-97-6	0.100
XIX	188	Ethylenediamine(EDA)	107-15-3	0.100
XIX	189	Lead*	7439-92-1	0.010
XIX	190	Octamethylcyclotetrasiloxane (D4)	556-67-2	0.100
XIX	191	Terphenyl, hydrogenated	61788-32-7	0.100
XX	192	1,7,7-trimethyl-3-(phenylmethylene)bicyclo[2.2.1]heptan-2-one (3-benzylidene camphor)	15087-24-8	0.100
XX	193	2,2-bis(4'-hydroxyphenyl)-4-methylpentane	6807-17-6	0.100
XX	194	Benzo[k]fluoranthene	207-08-9	0.100
XX	195	Fluoranthene	206-44-0, 93951-69-0	0.100
XX	196	Phenanthrene	85-01-8	0.100
XX	197	Pyrene	129-00-0, 1718-52-1	0.100
XXI	198	2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acyl halides (covering any of their individual isomers and combinations thereof)	-	0.100
XXI	199	2-methoxyethyl acetate	110-49-6	0.100
XXI	200	4-tert-butylphenol (PTBP)	98-54-4	0.100
XXI	201	Tris(4-nonylphenyl, branched and linear) phosphite (TNPP) with ≥ 0.1% w/w of 4-nonylphenol, branched and linear (4-NP)	-	0.100



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Test Report **SL22002253220301TX** Date: **May 20, 2020** Page 15 of 16

Appendix

Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
XXII	202	2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone	119313-12-1	0.100
XXII	203	2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one	71868-10-5	0.100
XXII	204	Diisohexyl phthalate	71850-09-4	0.100
XXII	205	Perfluorobutane sulfonic acid (PFBS) and its salts	-	0.100
/	206	1-vinylimidazole	1072-63-5	0.100
/	207	2-methylimidazole	693-98-1	0.100
/	208	Butyl 4-hydroxybenzoate	94-26-8	0.100
/	209	Dibutylbis(pentane-2,4-dionato-O,O')tin	22673-19-4	0.100
/	210	Resorcinol	108-46-3	0.100



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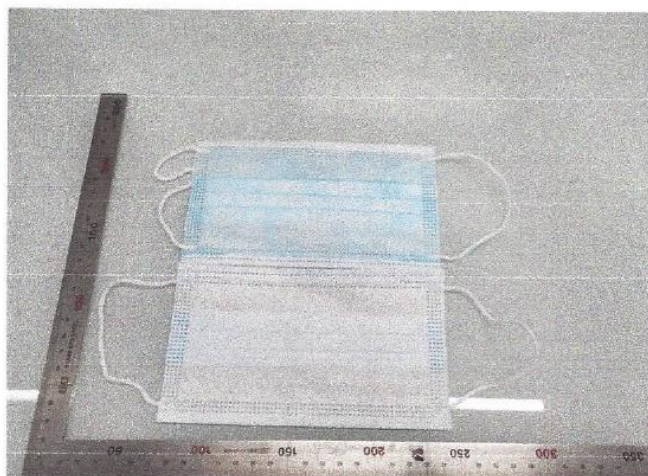
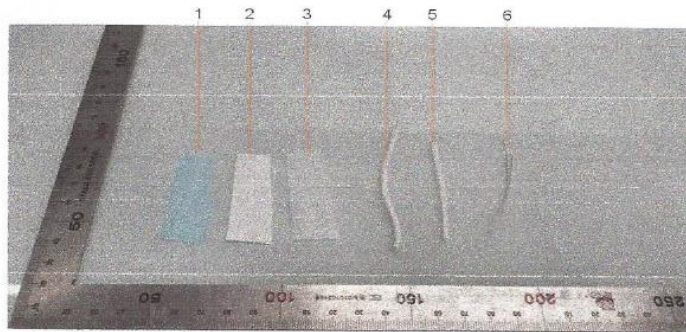


Test Report  
Sample photo:

SL22002253220301TX

Date: May 20, 2020

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The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

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**Test Report**                      **SL52035285528301TX**                      **Date: August 19, 2020**                      **Page 1 of 3**

SHANDONG POP JEANS INTELLIGENT MANUFACTURING CO.,LTD  
NO. 188, GENGJIAO ROAD, HUANTAI, ZIBO, SHANDONG, CHINA

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description : (A)SINGLE-USE MEDICAL FACE MASK

Brand : ASPOP

Composition : (A)Polypropylene

Sample Color : (A)Blue

Style No. : SN2020000301

Order No. : ILB-SDP-ANT-004 (batch code 2020080110)

Manufacturer : SHANDONG POP JEANS INTELLIGENT MANUFACTURING CO.,LTD

Agent : ILB

Country of Destination : EUR

Test Performed : Selected test(s) as requested by applicant

Sample Receiving Date : Aug 11, 2020

Testing Period : Aug 11, 2020 - Aug 19, 2020

Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Signed for and on behalf of  
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)



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Test Report SL52035285528301TX Date: August 19, 2020 Page 2 of 3

Test Result

**EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods**

**Clause 5.2 Performance Requirement**

**Clause 5.2.4 Splash Resistance**  
(ISO 22609 :2004)

Sample: A  
 Test Blood Pressure : 16.0kPa  
 Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.  
 Distance of the mask to the tip of cannula : 300±10mm

Test Specimen#	Penetration on inside surface	Conclusion	Test Specimen#	Penetration on inside surface	Conclusion
1	None Seen	Pass	17	None Seen	Pass
2	None Seen	Pass	18	None Seen	Pass
3	None Seen	Pass	19	None Seen	Pass
4	None Seen	Pass	20	None Seen	Pass
5	None Seen	Pass	21	None Seen	Pass
6	None Seen	Pass	22	None Seen	Pass
7	None Seen	Pass	23	None Seen	Pass
8	None Seen	Pass	24	None Seen	Pass
9	None Seen	Pass	25	None Seen	Pass
10	None Seen	Pass	26	None Seen	Pass
11	None Seen	Pass	27	None Seen	Pass
12	None Seen	Pass	28	None Seen	Pass
13	None Seen	Pass	29	None Seen	Pass
14	None Seen	Pass	30	None Seen	Pass
15	None Seen	Pass	31	None Seen	Pass
16	None Seen	Pass	32	None Seen	Pass
Number of Pass:			32		
Overall result:			Acceptable		

Remark:

- 1) Performance Requirement Type I: N/A, Type II: N/A, Type IIR: ≥16.0kPa
- 2) Test was conducted within 60s after removal from conditioning chamber.
- 3) An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show pass results.



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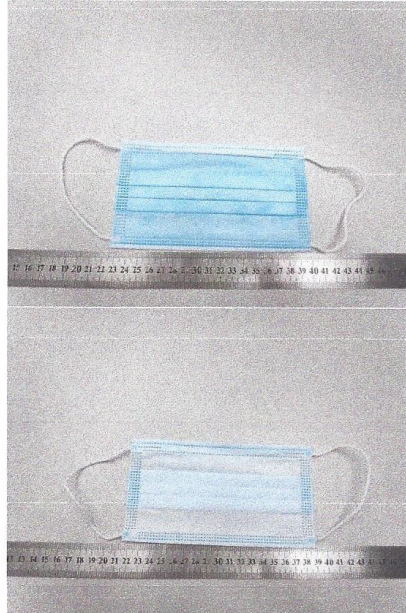
Test Report

SL52035285528301TX

Date: August 19, 2020

Page 3 of 3

Sample Photo



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**CE & EC-REP Deklaration**

## DECLARATION OF CONFORMITY

**According to Medical Device Regulation (MDR) 2017/745 Annex II and Annex III.**

<p><b>Manufacturer:</b>                  Name: Shandong POP Jeans Intelligent Manufacturing CO.,LTD                  Address: 188, Gengjiao Road, Huantai, Zibo, Shandong, China                  E-mail: michael@aspop.com.cn</p>	<p><b>Whose Authorized Representative:</b>                  Name: Lotus NL B.V.                  Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.                  E-mail: peter@lotusnl.com</p>
--	--

We, the manufacturer, herewith declare that the products

Product Name	Product ID Number	Medical Device	Device Class	Model	UMDNS Code	Basic UDI-DI
Single-use medical face mask (non-sterile)	SN2020003	Masks	IIR, Rule1 (Annex VIII of MDR)	Flat type	12447	

Passed the test conducted by SGS, with a test report Number of SL52025233812101TX, and meet the provisions of the Medical Device Regulation (MDR) 2017/745 which apply to them, and

**Conformity Assessment Route:** Annex II and Annex III according to MDR 2017/745.

**Applicable Standards:**

<i>EN 14683:2019</i>	<i>ISO 13485:2016</i>	<i>ISO 10993-1: 2018</i>
<i>ENISO 10993-5: 2009</i>	<i>ENISO 10993-10: 2013</i>	<i>ISO 14971:2019</i>
<i>EN 1041:2008</i>	<i>EN 29073-1:1992</i>	<i>EN ISO 9073-15-2008</i>
<i>EN 15223-1:2016</i>		

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Medical Device Regulation (MDR) 2017/745. We agree to develop, implement and maintain a documented post-production monitoring process.

Signed: 2020/7/20

Place: Shandong, China

Name of authorized signatory:

Position held in the company: General Manager

Seal/Stamp:

Shandong POP Jeans Intelligent Manufacturing CO.,LTD

**Hersteller ist nach amfori - BSCI Verhaltenscodex Zertifikat von Bureau Veritas zertifiziert (<https://ch.amfori.org/de>)**

**Producer :** Shandong Aspop Costumes Group Inc.

D8ID : 351951 and Audit Id : 156209  
Audit Type : Follow-up Audit

Audit Date : 05/07/2019



Trade with purpose

---

Auditee :	<b>Shandong Aspop Costumes Group Inc.</b>
Audit Date From :	<b>05/07/2019</b>
Audit Date To :	<b>05/07/2019</b>
Expiry Date of the Audit :	<b>Please refer to the producer profile in the amfori BSCI platform</b>
Auditing Company :	<b>BureauVeritas</b>
Auditor's Name(s) :	<b>Michael Ma(Lead), Jordan LI</b>
Auditing Branch (If applicable) :	



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**ISO 9001 / 14001**



GUOJIAN CERTIFICATION CO., LTD.

**ENVIRONMENTAL MANAGEMENT SYSTEM CERTIFICATE**

No: 174E200089R0M

*This is to certify that the Environmental Management system of*

**SHANDONG POP JEANS INTELLIGENT MANUFACTURING CO.,LTD.**  
NO.188,GENGJIAO ROAD,TANGSHAN TOWN,HUANTAI COUNTY,ZIBO CITY,SHANDONG PROVINCE

*Unified Social Credit Code: 913703213342969729*

**Environmental Management System**

*Has been awarded this certificate for compliance with the standard*

**GB/T 24001-2016/ISO 14001:2015**

*This Environmental Management System is valid for the*

**THE RELATIVE MANAGEMENT ACTIVITIES OF RESEARCH & DEVELOPMENT, PRODUCTION AND SALE OF PERSONALIZED CUSTOMIZED CLOTHING; PRODUCTION AND SALE OF ASPOP BRAND CLOTHING; PRODUCTION AND SALE OF NON-MEDICAL DISPOSABLE ISOLATION GOWN**  
(If the above scope involves pre-approval of administration permission and compulsory certification, this certificate only covers products/services in the approved / certified scope.)

Date of issue: 2020-06-22

Term of validity of this certificate: from 2020-06-22 to 2023-06-21

This certificate remains valid only if the certified organization accepts and passes regular surveillance audits

Scan the QR code to check the validity of the certificate



Representative of The Company





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CNAS C169-II



GUOJIAN CERTIFICATION CO., LTD.

**QUALITY MANAGEMENT SYSTEM CERTIFICATION**

No: 174Q200145R0M

*This is to certify that the quality system of*

**SHANDONG POP JEANS INTELLIGENT MANUFACTURING CO.,LTD.**  
NO.188,GENGJIAO ROAD,TANGSHAN TOWN,HUANTAI COUNTY,ZIBO CITY,SHANDONG PROVINCE

*Unified Social Credit Code: 913703213342969729*

**Quality Management System**

*Has been awarded this certificate for compliance with the standard*

**GB/T 19001-2016/ISO 9001:2015**

*This Quality Management System is valid for the*

**RESEARCH & DEVELOPMENT, PRODUCTION AND SALE OF PERSONALIZED CUSTOMIZED CLOTHING; PRODUCTION AND SALE OF ASPOP BRAND CLOTHING; PRODUCTION AND SALE OF NON-MEDICAL DISPOSABLE ISOLATION GOWN**  
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管理体系  
MANAGEMENT SYSTEM  
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**EMPA Prüfbericht Nr. 5214025580-G vom 22-09-2020**

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ILB Helios AG,  
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CH – 6300 Zug

**Prüfbericht Nr. 5214025580-G**

<b>Prüfauftrag</b>	<b>Analyse von Materialien für Community Masken</b>
Auftraggeber	ILB Helios AG, Chamerstrasse 175, CH – 6300 Zug
Probenahme	durch Auftraggeber
<b>Prüfobjekt</b>	<b>Aspop Masken, LOT 2020080110</b>
Kundenreferenz	Franz Portmann
Ihr Auftrag vom	27. August 2020
Eingang des Prüfobjektes	28. August 2020
Ausführung der Prüfung	31. August 2020 bis 18. September 2020
Anzahl Seiten	6
Beilagen	Regelung Werbung AGB Dienstleistungen Dokument SwissMedic Empfehlung National COVID-19 Science Task Force
Archivierung Material	Das restliche Prüfmaterial wird während 2 Jahren archiviert.

401 – ell/zep/ioma/bjoy/mha/tiv // Kontroll-Visum: *zep*

Empa, Swiss Federal Laboratories for Materials Science and Technology,  
Laboratory for Biomimetic Membranes and Textiles  
St. Gallen, 22. September 2020

Prüfleiterin



Leonie El Issawi-Frischknecht

Abteilungsleiter



Prof. Dr. René Rossi

Anmerkung Die Untersuchungsergebnisse haben nur Gültigkeit für das geprüfte Objekt. Bericht und Unterlagen werden 10 Jahre archiviert.

g:\bericht\1\_1\_remas\5214025580\_ilb\_helios\_ag\5214025580\_g\_ilb\_helios\_ag.docx

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**1. Geprüftes Material (dekl.)**

Art Name	Empa Nummer	Farbe	Materialbeschreibung
<b>Aspop Masken, LOT 2020080110</b>	1	blau	Single-Use Medical Face Mask, LOT 2020080110
Erhaltenes Material		50 Masken	

**1.1 Bilder des Materials**

**2. Bestimmung der Luftdurchlässigkeit in Anlehnung an ISO 9237 (inkl. Berechnung der Druckdifferenz in Anlehnung an EN 14683:2019-10)**

Mit einem Sauggebläse wird ein definierter Unterdruck erzeugt. Dies führt zu einem Luftfluss durch das aufgelegte und fixierte Material, welche gemessen wird. Basierend auf 10 Messungen wird der Ergebnisbereich bestimmt, welcher die Messunsicherheit der Methode mitberücksichtigt.

**2.1 Prüfbedingungen**

Art der Messung	Luftdurchflussmessung
Unterdruck	30Pa / 150Pa / 250Pa
Prüffläche	4.9 cm <sup>2</sup>
Prüfklima	≥ 4h bei (21 ± 3) °C und (85 ± 5)% rel. Lf.
Anzahl Messungen	10
Lage der Probe	Innenseite gegen Unterdruck
Zustand der Proben	Anlieferungszustand



### 3. Druck des Spritzwiderstandes in Anlehnung an ISO 22609

Das Prüfobjekt wird auf einem Objekthalter, wie in ISO 22609 beschrieben, aufgebracht. Eine definierte Menge an eingefärbtem synthetischem Speichel ( $2.01 \pm 0.04$  g) wird horizontal auf die Aussenseite des Prüfobjekts gesprüht (gesichtsabgewandte Seite). Zusätzlich zur Flüssigkeitsmenge ist die Entfernung zum Aufprall, die Grösse der Blende und die Geschwindigkeit der Flüssigkeit in kontrolliert. Das Prüfobjekt wird bei 12kPa geprüft, was dem Druck beim Husten entspricht. Das Durchdringen von synthetischem Speichel bis auf die Innenseite (Gesichtsseite) des Prüfobjekts wird visuell mit Hilfe eines Kosmetiktuchs festgestellt. Wird das Kosmetiktuch befeuchtet, gilt der Test als "nicht bestanden". Bleibt das Kosmetiktuch trocken, gilt der Test als "bestanden".

#### 3.1 Prüfbedingungen

Prüffläche	4.9 cm <sup>2</sup>
Prüfklima	≥ 4h bei (21 ± 3) °C und (85 ± 5)% rel. Lf.
Prüfdruck	12kPa
Prüfflüssigkeit	Synthetischer Speichel rot eingefärbt
Flüssigkeitsmenge	2.01 ± 0.04 g
Anzahl Messungen	10
Lage der Probe	Aussenseite gegen die Spritzdüse
Zustand der Proben	Anlieferungszustand

### 4. Partikelfiltrationseffizienz

Ein kreisförmiges Muster des Prüfobjekts/textilen Fläche mit Durchmesser von 4.6 cm (Probendurchmesser 6 cm) wird gemessen. Ein neutralisiertes und getrocknetes Aerosol aus Zuckerpartikeln mit einer Größenverteilung über 20 bis 3000 nm Durchmesser und einer Konzentration von  $8-9 \cdot 10^5$  dN/dlogD<sub>p</sub>/cm<sup>3</sup> (normierte Partikelanzahl über die Detektorbandbreite) bei der Partikelgröße höchster Intensität (240 nm) wird über die Probe geleitet. Durch ein Pumpensystem wird ein konstanter Luftdurchfluss von 8 l/min (8 cm/s) durch das Prüfobjekt/die textile Fläche gewährleistet, welcher dem Atemminutenvolumen bei leichter physischer Beanspruchung entspricht und sich an der Norm DIN EN 14683 orientiert. Die durch das Prüfobjekt/die textile Fläche diffundierenden Partikel werden in Echtzeit über ein Partikelmessgerät 'Cambustion DMS500' quantifiziert. Die Partikelfiltrationseffizienz ergibt sich aus den festgestellten Partikelflüssen ohne und mit Prüfobjekt/textile(r) Fläche, nachdem sich ein konstanter Partikelfluss eingestellt hat (nach ca. 2.5 Minuten Exposition) und wird in % über die Bereiche 100 (55-205) nm, 500 (205-750) nm, 1000 (750-1540) nm und 2000 (1540-2740) nm angegeben.

#### 4.1 Prüfbedingungen

Prüffläche	16.6 cm <sup>2</sup>
Prüfluftfluss	8 l/min (8 cm/s)
Prüfaerosol	Zuckerlösung (1.5 g/ml) in 24 l/min Luftfluss, neutralisiert
Prüfdauer	ca. 3 min, davon letzte 30 s
Prüfkonzentration	$8-9 \cdot 10^5$ dN/dlogD <sub>p</sub> /cm <sup>3</sup> pro Sekunde bei 240 nm Maximum
Anzahl Messungen	5
Lage der Probe	Aussenseite (farbig/glatt/markiert) Richtung Einlass
Zustand der Proben	Anlieferungszustand

**5. Resultate**

**5.1 Anforderungen gemäss Nationalen COVID-19 Science Task Force**

Die Maske erfüllt die Anforderungen, wenn folgende Vorgaben erfüllt werden:

- Druckdifferenz  $\leq 60$  [Pa/cm<sup>2</sup>]
- Druck des Spitzwiderstandes 10 von 10 bestanden bei 12kPa
- Partikelfiltrationseffizienz (1µm)  $\geq 70\%$

**5.2 Druckdifferenz in Anlehnung an ISO 9237 und in Anlehnung an EN 14683:2019-10**

Art. Name	Druckdifferenz [Messbereich] [Pa/cm <sup>2</sup> ]
<b>Aspop Masken, LOT 2020080110</b>	36.3 [34.2; 38.4]

Tabelle 1: Resultate Druckdifferenz. Der Messbereich gibt den Streuungsbereich der Daten an (+/- 1 Standardabweichung festgestellt bei 10 Messungen) Die Anforderung gilt als erfüllt, wenn der Messbereich die geforderte Druckdifferenz mindestens miteinschliesst. Messergebnisse, welche nicht den Anforderungen entsprechen, sind gelb markiert.

**5.3 Druck des Spritzwiderstandes in Anlehnung an ISO 22609**

Art. Name	Bestandene Muster bei einem Druck des Spritzwiderstandes von 12kPa
<b>Aspop Masken, LOT 2020080110</b>	10 von 10 bestanden

Tabelle 2: Resultate Druck des Spritzwiderstandes. Messergebnisse, welche nicht den Anforderungen entsprechen, sind gelb markiert.

Bild Druck des Spritzwiderstandes



**5.4 Partikelfiltrationseffizienz**

Art. Name	Ergebnis Partikelfiltrationseffizienz [Ergebnisbereich] in % für			
	100 nm	500 nm	1 µm	2 µm
<b>Aspop Masken, LOT 2020080110</b>	88.6 [86.3; 91.0]	93.6 [92.0; 95.1]	97.7 [97.1; 98.4]	99.8 [99.6; 100]

Tabelle 3: Resultate Partikelfiltrationseffizienz. Der Messbereich gibt den Streubereich der Daten an (+/- 1 Standardabweichung festgestellt bei 5 Messungen) Die Anforderung gilt als erfüllt, wenn der Messbereich die geforderte Filtrationseffizienz mindestens miteinschliesst. Messergebnisse, welche nicht den Anforderungen entsprechen, sind gelb markiert.

**6. Ergebnis der durchgeführten Messanalysen**

Das geprüfte, ungewaschene Material **entspricht**, in Bezug auf die drei durchgeführten Tests und unter Berücksichtigung der Messunsicherheiten, der Empfehlung der Nationalen COVID-19 Science Task Force. Die Waschbarkeit (Reusability) sowie die Biokompatibilität (Innocuity of the materials) wurden in diesem Prüfauftrag nicht untersucht.

**7. Sorgfalt und Haftung:**

Die Empa leistet Gewähr für eine sorgfältige, dem aktuellen Stand von Wissenschaft und Technik entsprechende Ausführung der Materialanalysen. Die Messergebnisse beziehen sich nur auf das vom Auftraggeber zur Verfügung gestellte bzw. auf das von der Empa untersuchte Probematerial. Die Empa übernimmt keine Gewähr dafür, dass die Messergebnisse auch für andere Lieferungen des gleichen Materials, Stoffes usw. zutreffen. Die Haftung, gleich aus welchem Rechtsgrund, insbesondere für leichte Fahrlässigkeit, indirekte Schäden und Folgeschäden, wird wegbedungen, soweit dies gesetzlich zulässig ist.

**8. Verwendung des Berichts**

Die vorliegende Materialanalyse stellt keine Zertifizierung des Produktes des Auftraggebers dar. Der Bericht kann vom Auftraggeber gegenüber Dritten verwendet werden, um darzulegen, dass das Prüfobjekt von der Empa nach den Empfehlungen der Nationalen COVID-19 Science Task Force mit den hierin gemachten Ergebnissen analysiert wurde. Bei der Verwendung des Berichts und insbesondere bei Hinweisen in Werbematerialien ist die "Regelung Werbung mit Empa-Prüfberichten" (vgl. Beilage) einzuhalten. Die Werbebewilligung wird mit diesem Bericht für ein Jahr ab Unterzeichnungsdatum erteilt.

\* \* \* \* \*