

**SGS -Test EN 14683: 2019 + AC: 2019 and ISO 22609:2004 (Splash residency)**

			中国认可 国际互认 检测 TESTING CNAS L0599 Page 1 of 5
Test Report	SL52045300358001TX	Date: October 30, 2020	

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

Composition : (A)Polypropylene

Brand : ASPOP

Sample Color : (A)Black

Style No. : SN2020000301

Batch Number : 2020080813

Manufacturer : SHANDONG POP JEANS INTELLIGENT MANUFACTURING CO.,LTD

Country of Destination : EUR

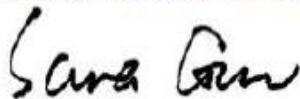
Test Performed : Selected test(s) as requested by applicant

Sample Receiving Date : Oct 15, 2020

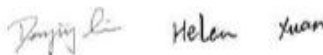
Testing Period : Oct 21, 2020 - Oct 30, 2020

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)

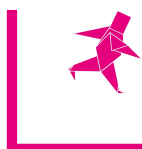


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Test Report

SL52045300358001TX

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**Clause 5.2.3 Breathability**

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

Sample: A

Test Side : Randomly test in different location (1 around and 4 away from the centric point) on each of the 5 masks

Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±6% R.H.

Test Area : 4.9 cm<sup>2</sup>

Flow Rate : 8 l/min

Specimen No.	Test Area No.	Different Pressure for each tested area (Pa/cm <sup>2</sup> )	The average value for each test specimen (Pa/cm <sup>2</sup> )
1	1-1	44.9	48
	1-2	49.1	
	1-3	45.0	
	1-4	51.0	
	1-5	47.0	
2	2-1	44.0	47
	2-2	45.7	
	2-3	46.7	
	2-4	47.4	
	2-5	48.2	
3	3-1	47.8	47
	3-2	47.1	
	3-3	46.9	
	3-4	47.4	
	3-5	45.7	
4	4-1	44.7	47
	4-2	51.1	
	4-3	47.9	
	4-4	48.9	
	4-5	44.2	
5	5-1	47.0	48
	5-2	47.0	
	5-3	51.4	
	5-4	48.7	
	5-5	46.9	

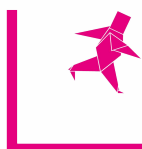
**Remark:**

- 1) Performance Requirement: Type I<40 Pa/cm<sup>2</sup>, Type II<40 Pa/cm<sup>2</sup>, Type IIR<80 Pa/cm<sup>2</sup>
- 2) The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL(Acceptable Quality Level) of 4%.



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Testing Center, Antalis Services Co., Ltd. | 中国 - 上海 - 静安区宝山湾688号3号楼 邮编: 200235 | (86-21) 61488888 | (86-21) 64958163 | e: [sgs.china@sgs.com](mailto:sgs.china@sgs.com)

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**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

SL52045300358001TX

Date: October 30, 2020

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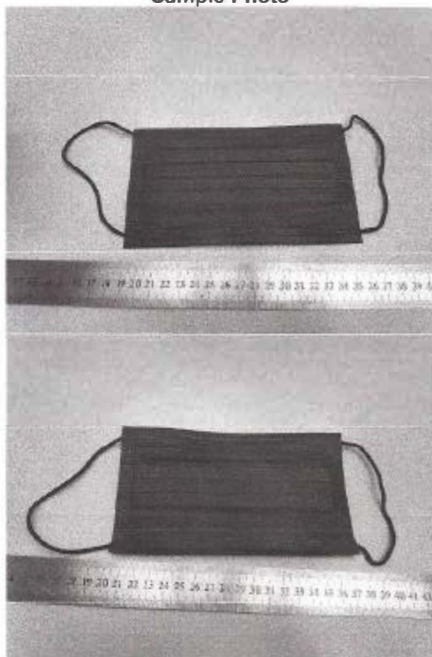
**Clause 5.2.5 Microbial Cleanliness**  
(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

Sample: A

Test Specimen#	Mask Weight(g)	Total Bioburden, (CFU/mask)	Total Bioburden, (CFU/g)
1#	3.27	6	1.83
2#	3.28	18	5.49
3#	3.28	<3	<0.91
4#	3.25	27	8.31
5#	3.24	<3	<0.93

Remark: Performance Requirement: Type I ≤ 30 CFU/g, Type II ≤ 30 CFU/g, Type IIR ≤ 30 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.

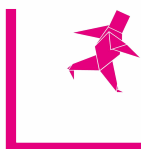
\*\*\*End of Report\*\*\*



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**CE & EC-REP declaration**



## 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	Color	Device Class	Model	UMDNS Code	Basic UDI-DI
Single-use medical face mask (non-sterile)	SN2020000301	Masks	Black	IIR, Rule1 (Annex VIII of MDR)	Flat type	12447	

Passed the test conducted by SGS, with a test report Number of SL52045300358001TX, and meet the provisions of the Medical Device Regulation (MDR) 2017/745 which apply to them.

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

**Applicable Standards:**

<i>EN 14683:2019+AC: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: 2020/11/02



Place: Shandong, China

**Name of authorized signatory:**

**Position held in the company:** General Manager

**Seal/Stamp:**

Shandong POP Jeans Intelligent Manufacturing CO.,LTD



**The manufacturer is certified by Bureau Veritas according to amfori - BSCI Code of Conduct**

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

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

Audit Date : 05/07/2019



---

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

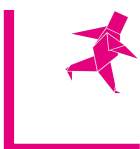
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*Unified Social Credit Code: 913703213342969729*

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

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

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**Prüfbericht Nr. 5214025863-G**

<b>Prüfauftrag</b>	<b>Analyse von Materialien für Community Masken</b>
Auftraggeber	
Probenahme	durch Auftraggeber
<b>Prüfobjekt</b>	<b>Aspop Masken, LOT 20200080813</b>
Kundenreferenz	
Ihr Auftrag vom	13. Oktober 2020
Eingang des Prüfobjektes	13. Oktober 2020
Ausführung der Prüfung	14. Oktober 2020 bis 27. Oktober 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/bjoy/mha/riv/hego // Kontroll-Visum: *zep*

Empa, Swiss Federal Laboratories for Materials Science and Technology,  
Laboratory for Biomimetic Membranes and Textiles  
St. Gallen, 29. Oktober 2020

Prüfleiterin

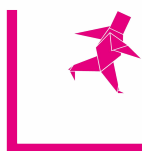
Leonie El Issawi-Frischknecht

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



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## 1. Geprüftes Material (dekl.)

Art. Name	Empa Nummer	Farbe	Materialbeschreibung
<b>Aspop Masken, LOT 20200080813</b>	1	schwarz	Einweg medizinische OP Gesichtsmaske Hersteller: Shandong POP Jeans Intelligent Manufacturing Co., LTD
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 (87-205) 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	≤ 60 [Pa/cm <sup>2</sup> ]
Druck des Spritzwiderstandes	10 von 10 bestanden bei 12kPa
Partikelfiltrationseffizienz (1µm)	≥ 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 20200080813</b>	42.5 [40.0; 45.0]

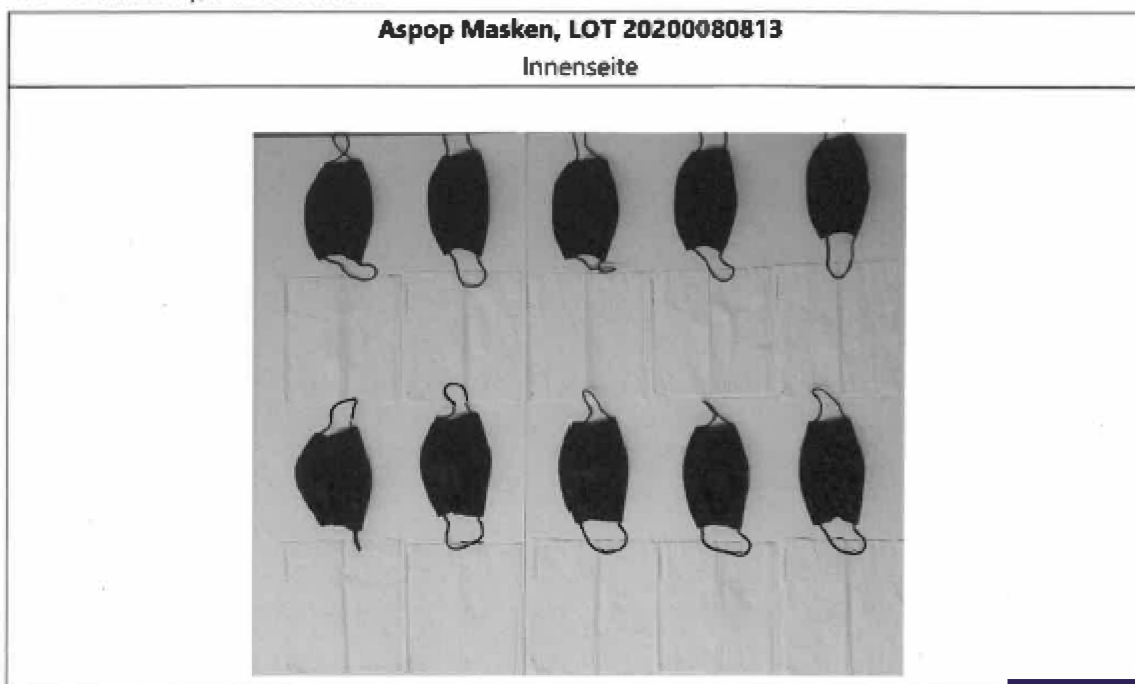
Tabelle 1: Resultate Druckdifferenz. Der Messbereich gibt den Streubereich der Daten an (+/- 1 Standardabweichung festgestellt bei 10 Messungen) Die Anforderung gilt als erfüllt, wenn der Messbereich die geforderte Druckdifferenz mindestens miteinschliesst. Messergebnisse, welche nicht den Anforderungen 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 20200080813</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 [Messbereich] In % für			
	100 nm	500 nm	1 µm	2 µm
<b>Aspop Masken, LOT 20200080813</b>	93.0 [92.2; 93.8]	96.6 [96.1; 97.0]	99.5 [99.4; 99.6]	100.0 [100.0; 100.0]

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.

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