

# Test Report

No. TSNHG2001258601

Date: 07 Aug 2020

Page 1 of 7

HEBEI TITANS HONGSEN MEDICAL TECHNOLOGY CO.,LTD.

EASTERN INDUSTRIAL ZONE,NANGONG CITY,XINGTAI CITY,HEBEI,CHINA

The following sample(s) was/were submitted and identified on behalf of the clients as : DISPOSABLE PVC GLOVES

SGS Job No. : TJHL2007004565CW - TJ  
 Manufacturer : HEBEI TITANS HONGSEN MEDICAL TECHNOLOGY CO.,LTD.  
 Country of Origin : CHINA  
 Country of Destination : CHINA/EU/USA  
 Date of Sample Received : 17 Jul 2020  
 Testing Period : 17 Jul 2020 - 07 Aug 2020  
 Test Requested : Selected test(s) as requested by client.  
 Test Method : Please refer to next page(s).  
 Test Results : Please refer to next page(s).

## Result Summary :

Test Requested	Conclusion
Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments– Overall migration	PASS
Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 –Sensorial examination odour and taste test	PASS
Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments – Specific Migration of Phthalates	PASS
Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments – Specific Migration of Bisphenol A	PASS
Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments – Specific Migration of Heavy Metal	PASS
Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments – Vinyl chloride monomer	PASS
Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments – Phthalates	PASS



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested.

Attention: To check the authenticity of testing /inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: [CN.Doccheck@sgs.com](mailto:CN.Doccheck@sgs.com)

SGS Mansion, No.41, The 5th Avenue TEDA, Tianjin, China 300457  
 中国·天津市经济技术开发区第五大街41号SGS大厦 邮编: 300457

t (86-22) 65288000 www.sgsgroup.com.cn  
 t (86-22) 65288000 sgs.china@sgs.com

## Test Report

No. TSNHG2001258601

Date: 07 Aug 2020

Page 2 of 7

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



scan to see the report



TSNHG2001258601

Reabeca Zhou  
Approved Signatory



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Document.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested.

Attention: To check the authenticity of testing / inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: [CN.Doccheck@sgs.com](mailto:CN.Doccheck@sgs.com)

SGS Mansion, No.41, The 5th Avenue TEDA, Tianjin, China 300457  
中国·天津市经济技术开发区第五大街41号SGS大厦 邮编: 300457

t (86-22) 65288000 www.sgsgroup.com.cn  
t (86-22) 65288000 sgs.china@sgs.com

## Test Report

No. TSNHG2001258601

Date: 07 Aug 2020

Page 3 of 7

Test Results :

### Test Part Description :

Specimen No.	SGS Sample ID	Description	Material (claimed by the client)
SN1	TSN20-012586.001	translucent plastic gloves	PVC

Remarks :

- (1) mg/dm<sup>2</sup> = milligram per square decimeter
- (2) mg/kg = milligram per kilogram
- (3) °C= degree Celsius
- (4) < = less than
- (5) MDL = Method Detection Limit
- (6) ND = Not Detected ( < MDL)

### Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments– Overall migration

Test Method : With reference to Commission Regulation (EU) No 10/2011 of 14 January 2011 Annex III and Annex V for selection of condition and EN 1186-1:2002 for selection of test methods;  
or EN 1186-3:2002 aqueous food simulants by total immersion method;

<u>Simulant Used</u>	<u>Time</u>	<u>Temperature</u>	<u>Max. Permissible Limit</u>	<u>Result of 001 Overall Migration</u>
10% Ethanol (V/V) Aqueous Solution	2.0hr(s)	70°C	10mg/dm <sup>2</sup>	<3.0mg/dm <sup>2</sup>
3% Acetic Acid (W/V) Aqueous Solution	2.0hr(s)	70°C	10mg/dm <sup>2</sup>	<3.0mg/dm <sup>2</sup>

Notes :

- (1) Analytical tolerance of aqueous simulants is 2 mg/dm<sup>2</sup>.
- (2) Test condition & simulant were specified by client.
- (3) Report the first migration result.

### Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 –Sensorial examination odour and taste test

Test Method : With reference to DIN 10955:2004  
Test media: Distilled water  
No. of panelist: 6



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested.

Attention: To check the authenticity of testing /inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: [CN.Doccheck@sgs.com](mailto:CN.Doccheck@sgs.com)

SGS Mansion, No.41, The 5th Avenue TEDA, Tianjin, China 300457  
中国·天津市经济技术开发区第五大街41号SGS大厦 邮编: 300457

t (86-22) 65288000 www.sgsgroup.com.cn  
t (86-22) 65288000 sgs.china@sgs.com

## Test Report

No. TSNHG2001258601

Date: 07 Aug 2020

Page 4 of 7

<u>Test Item(s)</u>	<u>Limit</u>	<u>001</u>
Test time (hr(s))	-	2.0
Test Temperature (°C)	-	70
Sensorial examination odour	2.5	0.0
Sensorial examination taste	2.5	0.0
<b>Conclusion</b>		<b>PASS</b>

### Notes :

Intensity scale (rounded at 0.5):

- 0 – no perceptible difference
- 1 – just perceptible difference
- 2 – slight difference
- 3 – marked difference
- 4 – strong difference

### Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments – Specific Migration of Phthalates

Test Method : With reference to EN13130-1:2004, analysis was performed by GC-MS.

### Sample 001

Simulant Used : 3% Acetic Acid (W/V) Aqueous Solution

Test Condition : 70 °C 2.0 hr(s)

<u>Test Item(s)</u>	<u>CAS NO.</u>	<u>Max. Permissible</u> <u>Limit</u>	<u>Unit</u>	<u>MDL</u>	<u>Test result</u>
Migration times		-	-	-	First
Area/volume		-	dm <sup>2</sup> /kg	-	6.0
Benzylbutyl Phthalate(BBP)	85-68-7	30	mg/kg	0.05	ND
Dibutyl Phthalate(DBP)	84-74-2	0.3	mg/kg	0.05	ND
Bis-(2-ethylhexyl) Phthalate(DEHP)	117-81-7	1.5	mg/kg	0.05	ND
Diisononyl phthalate + Diisodecyl phthalate (DINP+DIDP)	-	9.00	mg/kg	0.20	ND
Diallyl Phthalate(DAP)	131-17-9	0.01	mg/kg	0.01	ND

### Notes :

Test condition & simulant were specified by client.



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested.

Attention: To check the authenticity of testing /inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: [CN.Doccheck@sgs.com](mailto:CN.Doccheck@sgs.com)

SGS Mansion, No.41, The 5th Avenue TEDA, Tianjin, China 300457  
中国·天津市经济技术开发区第五大街41号SGS大厦 邮编: 300457

t (86-22) 65288000 www.sgsgroup.com.cn  
t (86-22) 65288000 sgs.china@sgs.com

# Test Report

No. TSNHG2001258601

Date: 07 Aug 2020

Page 5 of 7

## Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments –Specific Migration of Bisphenol A

Test Method : With reference to EN13130-1:2004, analysis was performed by HPLC-FLD.

### Sample 001

Simulant Used : 3% Acetic Acid (W/V) Aqueous Solution

Test Condition : 70 °C 2.0 hr(s)

<u>Test Item(s)</u>	<u>Max. Permissible</u> <u>Limit</u>	<u>Unit</u>	<u>MDL</u>	<u>Test result</u>
Migration times	-	-	-	First
Area/volume	-	dm <sup>2</sup> /kg	-	6.0
Specific migration of Bisphenol-A	0.05	mg/kg	0.01	ND

Notes :

Test condition & simulant were specified by client.

## Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments –Specific Migration of Heavy Metal

Test Method : With reference to EN13130-1:2004, analysis was performed by ICP-OES.

### Sample 001

Simulant Used : 3% Acetic Acid (W/V) Aqueous Solution

Test Condition : 70 °C 2.0 hr(s)

<u>Test Item(s)</u>	<u>Max. Permissible</u> <u>Limit</u>	<u>Unit</u>	<u>MDL</u>	<u>Test result</u>
Migration times	-	-	-	First
Area/volume	-	dm <sup>2</sup> /kg	-	6.0
Barium	1	mg/kg	0.25	ND
Cobalt	0.05	mg/kg	0.01	ND
Copper	5	mg/kg	0.25	ND
Iron	48	mg/kg	0.25	ND
Lithium	0.6	mg/kg	0.5	ND
Manganese	0.6	mg/kg	0.25	ND
Zinc	5	mg/kg	0.5	ND
Aluminium	1	mg/kg	0.1	ND
Nickel	0.02	mg/kg	0.01	ND



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Document.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested.

Attention: To check the authenticity of testing /inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: [CN.Doccheck@sgs.com](mailto:CN.Doccheck@sgs.com)

SGS Mansion, No.41, The 5th Avenue TEDA, Tianjin, China 300457  
中国·天津市经济技术开发区第五大街41号SGS大厦 邮编: 300457

t (86-22) 65288000 www.sgsgroup.com.cn  
t (86-22) 65288000 sgs.china@sgs.com



# Test Report

No. TSNHG2001258601

Date: 07 Aug 2020

Page 6 of 7

## Notes :

- (1) Test condition & simulant were specified by client.

## Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments –Vinyl chloride monomer

Test Method : SGS In house method, analysis was performed by HS-GC-MS.

<u>Test Item(s)</u>	<u>Limit</u>	<u>Unit</u>	<u>MDL</u>	<u>001</u>
VCM(Vinyl Chloride Monomer)	1	mg/kg	0.5	ND

## Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments – Phthalates

Test Method : Solvent extraction, analysis was performed by GC-MS.

<u>Test Item(s)</u>	<u>CAS NO.</u>	<u>Limit</u>	<u>Unit</u>	<u>MDL</u>	<u>001</u>
Dibutyl Phthalate (DBP)	84-74-2	0.05	% (w/w)	0.003	ND
Benzylbutyl Phthalate (BBP)	85-68-7	0.1	% (w/w)	0.003	ND
Bis-(2-ethylhexyl) Phthalate (DEHP)	117-81-7	0.1	% (w/w)	0.003	ND
Diisononyl Phthalate (DINP)	28553-12-0/ 68515-48-0	0.1	% (w/w)	0.01	ND
Diisodecyl Phthalate (DIDP)	26761-40-0/ 68515-49-1	0.1	% (w/w)	0.01	ND



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested.

Attention: To check the authenticity of testing /inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: [CN.Doccheck@sgs.com](mailto:CN.Doccheck@sgs.com)

SGS Mansion, No.41, The 5th Avenue TEDA, Tianjin, China 300457  
中国·天津市经济技术开发区第五大街41号SGS大厦 邮编: 300457

t (86-22) 65288000 www.sgsgroup.com.cn  
t (86-22) 65288000 sgs.china@sgs.com

## Test Report

No. TSNHG2001258601

Date: 07 Aug 2020

Page 7 of 7

Sample photo:



SGS authenticate the photo on original report only

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



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested.

Attention: To check the authenticity of testing /inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: [CN.Doccheck@sgs.com](mailto:CN.Doccheck@sgs.com)

SGS Mansion, No.41, The 5th Avenue TEDA, Tianjin, China 300457  
中国·天津市经济技术开发区第五大街41号SGS大厦 邮编: 300457

t (86-22) 65288000 www.sgsgroup.com.cn  
t (86-22) 65288000 sgs.china@sgs.com