

Test Report Date: 16 Aug 2022 No. NGBHG2201873901 Page 1 of 6

NINGBO TRANSO-MEDICAL CO., LTD. Client Name:

Client Address: ROOM 1608, NO.18 DIAMOND COMMERCIAL PLAZA, NO.409 JIANG'AN ROAD, JIANGBEI

DISTRICT, NINGBO CITY, ZHEJIANG PROVINCE, P.R. CHINA

Sample Name: PE GLOVES

Item No.: NOT PROVIDED

Country of Origin: **CHINA**

Style No.: **NOT PROVIDED**

Υ

The above sample(s) and information were provided by the client.

SGS Job No.: NBHL2208015673CW - NB

10 Aug 2022 Date of Sample Received:

Testing Period: 10 Aug 2022 - 16 Aug 2022

Test Requested: Selected test(s) as requested by the client.

Test Method(s): Please refer to next page(s). Test Result(s): Please refer to next page(s).

Result Summary:

| Test Requested | Conclusion |
|--|------------|
| (EU) No 10/2011 and its amendment (EU) 2020/1245 Regulation-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 |
| (EU) No 10/2011 and its amendment (EU) 2020/1245 Regulation -Specific migration of heavy metal | PASS |
| Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments-Phthalates | PASS |



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Signed for and on behalf of SGS-CSTC Standards Technical Services Co., Ltd. Ningbo Branch

Iris Xiao

Approved Signatory

影玲艳



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Test Result(s):

Test Part Description:

Specimen No. SGS Sample ID Description Material (claimed by the client)

PΕ SN₁ NGB22-018739.001 Transparent plastic glove

Remarks:

(1) mg/dm² = 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)

(EU) No 10/2011 and its amendment (EU) 2020/1245 Regulation-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;

EN 1186-9: 2002 aqueous food simulants by article filling method;

EN 1186-14: 2002 substitute test;

| Simulant Used | <u>Time</u> | <u>Temperature</u> | Max. Permissible <u>Limit</u> | Result of 001 Overall migration | Conclusion |
|---|-------------|--------------------|----------------------------------|----------------------------------|------------|
| 3% Acetic acid (W/V) aqueous solution (First migration) | 2.0hr(s) | 70°C | 10mg/dm² | <3.0mg/dm² | PASS |
| Isooctane (First migration) | 0.5hr(s) | 40°C | 10mg/dm ² | <3.0mg/dm² | PASS |
| 95% Ethanol (First migration) | 2.0hr(s) | 60°C | 10mg/dm² | <3.0mg/dm² | PASS |
| 10% Ethanol (V/V) Aqueous Solution (First migration) | 2.0hr(s) | 70°C | 10mg/dm² | <3.0mg/dm² | PASS |
| Area/Volume | | | - | 25.7dm²/kg | |

Notes:

- (1) Analytical tolerance of aqueous simulants is 2 mg/dm².
- (2) Analytical tolerance of fatty food simulants is 3 mg/dm².

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(3) Test condition & simulant were specified by client.



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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

| Test Item(s) | <u>Limit</u> | <u>001</u> |
|---|--------------|------------|
| Test time(hr) | - | 1 |
| Temperature(°C) | - | 40 |
| Sensorial examination odour (Point scale) | 2.5 | 0 |
| Sensorial examination taste (Point scale) | 2.5 | 0 |
| Conclusion | | PASS |

Notes:

Scale evaluation:

0 – no perceptible difference

1 – just perceptible difference

2 - slight difference

3 - marked difference

4 - strong difference

(EU) No 10/2011 and its amendment (EU) 2020/1245 Regulation -Specific migration of heavy metal

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

Sample 001

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

Test Condition: 40 °C 1.0 hr(s)

| Test Item(s) | Max. Permissible Limit | <u>Unit</u> | <u>MDL</u> | Test result |
|-----------------|---------------------------|-------------|------------|-------------|
| Migration times | - | - | - | First |
| Area/volume | - | dm²/kg | - | 6.0 |
| Arsenic(As) | ND | mg/kg | 0.01 | ND |
| Cadmium(Cd) | ND | mg/kg | 0.002 | ND |
| Chromium (Cr) | ND | mg/kg | 0.01 | ND |
| Mercury(Hg) | ND | mg/kg | 0.01 | ND |
| Lead(Pb) | ND | mg/kg | 0.01 | ND |
| Aluminium (AI) | 1 | mg/kg | 0.1 | ND |
| Barium (Ba) | 1 | mg/kg | 0.25 | ND |



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|----------------------------------|---------------------|--------------|-------------------|------|
| Cobalt (Co) | 0.05 | mg/kg | 0.01 | ND |
| Copper (Cu) | 5 | mg/kg | 0.25 | ND |
| Iron(Fe) | 48 | mg/kg | 5 | ND |
| Lithium (Li) | 0.6 | mg/kg | 0.1 | ND |
| Manganese(Mn) | 0.6 | mg/kg | 0.1 | ND |
| Zinc(Zn) | 5 | mg/kg | 0.5 | ND |
| Nickel (Ni) | 0.02 | mg/kg | 0.01 | ND |
| Antimony (Sb) | 0.04 | mg/kg | 0.01 | ND |
| Europium (Eu) | - | mg/kg | 0.025 | ND |
| Gadolinium(Gd) | - | mg/kg | 0.025 | ND |
| Lanthanum(La) | - | mg/kg | 0.025 | ND |
| Terbium(Tb) | - | mg/kg | 0.025 | ND |
| Europium (Eu)+ Gadolinium(Gd)+ L | anthanum(La)+ 0.05 | mg/kg | - | ND |
| Terbium(Tb) | | | | |
| Conclusion | | | | PASS |

Notes:

- (1) Test condition & simulant were specified by client.
- (2) The test is not accredited by CNAS.

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

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

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

Notes:

(1) The test is not accredited by CNAS.

Unless otherwise stated, the decision rule for conformity reporting is based on Binary Statement for Simple Acceptance Rule (w=0) stated in ILAC-G8:09/2019.



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Sample photo:



SGS authenticate the photo on original report only

*** End of Report ***





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