



**SUBJECT** Chemical 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** TANGSHAN LANHAI MEDICAL SUPPLIES CO., LTD

**CLIENT ADDRESS** SOUTH SIDE OF ZHONGDA STREET, EAST SIDE OF JINXIU ROAD, CHENGXI INDUSTRIAL ZONE, LUANNAN COUNTY, TANGSHAN CITY, HEBEI, CHINA

**TEST PERIOD** 11-May-2020~15-May-2020

**RESULT SUMMARY** The tested items **complied with** European COMMISSION REGULATION (EU) No 10/2011 and its amendments on plastic materials and articles intended to come into contact with food.

- Overall migration test(3% Acetic acid,20% Ethanol)
- Specific migration of Primary Aromatic Amine
- Specific migration of Heavy metals
- Vinyl Chloride Monomer (VCM) content
- Specific migration of Phthalates(BBP,DBP, DEHP, DINP, DIDP, DEHA, DAP)

PASS  
PASS  
PASS  
PASS  
PASS

Prepared By

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**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.



**RECEIPT DATE / TEST DATE**

11-May-2020/ 11-May-2020

**THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED**

**BY/ ON BEHALF OF THE CLIENTS AS**

Sample Name: Disposable vinyl gloves

Sample Specification: PFM

Batch No./Date: /

Manufacturer: /

| SAMPLE NO. | DESCRIPTION        | PHOTOGRAPH |
|------------|--------------------|------------|
| 721654303  | Transparent gloves |            |

**TEST RESULT(S)**

Note: The migration results in this report were tested and expressed based on single use articles

**1. Overall Migration Test**

- Test method: As specified in REGULATION (EU) No 10/2011 and its amendments; with reference to EN 1186: Part 5 (Test methods for overall migration into aqueous food simulants by cell)
- Migration ratio(S/V): 10 dm<sup>2</sup>/L

| Simulant(s) Used | Test Condition   | Result(s)<br>[mg/dm <sup>2</sup> ] | Maximum<br>Permissible Limit<br>[mg/dm <sup>2</sup> ] |
|------------------|------------------|------------------------------------|---|
| 3% Acetic acid   | 70°C for 2 hours | 0.850                              | 10  |
| 20% Ethanol      | 70°C for 2 hours | 1.35                               | 10  |

**2. Specific migration of Primary Aromatic Amine**

- Test method: With reference to EN 13130-1:2004, followed by Kunststoffe im Lebensmittelverkehr, Book 2, Teil B II, XXI
- Test condition: 3% Acetic acid, 40°C for 2 hours
- Migration ratio(S/V): 6 dm<sup>2</sup>/L

| Test Item(s)                                 | Result(s)<br>[mg/kg] | Maximum Permissible Limit<br>[mg/kg] |
|--|----------------------|--------------------------------------|
| Specific migration of Primary Aromatic Amine | <0.01                | 0.01                                 |



3. Specific Migration: Heavy metal – Al, Ba, Co, Cu, Fe, Li, Mn, Zn, Ni

- Test method: As specified in REGULATION (EU) No 10/2011 and its amendments; with reference to EN13130-1:2004, followed by ICP-MS.
- Test condition: 3% Acetic acid, 40°C for 2 hours
- Migration ratio(S/V): 6 dm<sup>2</sup>/L

| Test Item(s) | Result(s)<br>[mg/kg] | Limit<br>[mg/kg] |
|--------------|----------------------|------------------|
| Aluminum     | <0.1                 | 1                |
| Barium       | <0.1                 | 1                |
| Cobalt       | <0.05                | 0.05             |
| Copper       | <0.5                 | 5                |
| Iron         | <1.0                 | 48               |
| Lithium      | <0.1                 | 0.6              |
| Manganese    | <0.05                | 0.6              |
| Zinc         | <1.0                 | 5                |
| Nickel       | <0.002               | 0.02             |

4. Vinyl Chloride Monomer (VCM) content

- Test method: With reference to EN ISO 6401:2008 Plastics - Poly(vinyl chloride) - Determination of residual vinyl chloride monomer - Gas-chromatographic method

| Test Item(s)                            | Result(s)<br>[mg/kg] | Maximum<br>Permissible Limit<br>[mg/kg] |
|---|----------------------|---|
| Vinyl Chloride Monomer (VCM)<br>content | <0.1                 | 1                                       |

5. Specific migration of Phthalates

- Test method: In according with REGULATION (EU) No 10/2011; With reference to EN 13130-1:2004, followed by GC-MS analysis
- Test condition: 20% Ethanol, 40°C for 2 hours
- Migration ratio(S/V): 6 dm<sup>2</sup>/L

| Test Item(s)                     | CAS No.    | Result(s)<br>[mg/kg] | Maximum Permissible<br>Limit [mg/kg] |
|----------------------------------|------------|----------------------|--------------------------------------|
| Benzylbutyl Phthalate(BBP)       | 85-68-7    | <0.25                | 30                                   |
| Dibutyl Phthalate(DBP)           | 84-74-2    | <0.2                 | 0.3                                  |
| Di(2-ethylhexyl) Phthalate(DEHP) | 117-81-7   | <0.25                | 1.5                                  |
| Diisononyl Phthalate(DINP)       | 68515-48-0 | <1.00                | 9                                    |
| Diisodecyl Phthalate(DIDP)       | 26761-40-0 | <1.00                |                                      |
| Bis(2-ethylhexyl) adipate(DEHA)  | 103-23-1   | <0.1                 | 18                                   |
| Diallyl phthalate(DAP)           | 131-17-9   | ND                   | Not Detected (DL:0.01)               |

- Note:
1. DL denotes Detection Limit
  2. ND denotes Not Detected and less than detection Limit

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

-END OF THE TEST REPORT-