



**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** Shandong Intco Medical Products Co., Ltd.

**CLIENT ADDRESS** No.9888 Qiwang Road,Naoshan Industry Park,Qingzhou,Shandong,China

**TEST PERIOD** 22-Jan-2021~03-Feb-2021

**RESULT SUMMARY**

The tested items were found to **complied with** European COMMISSION REGULATION (EU) No 2020/1245, (EU) No 10/2011 and its amendments on plastic materials and articles intended to come into contact with food.

- Specific migration of 22 Primary Aromatic Amine
- Specific migration of Heavy metals

**PASS**

**PASS**

Prepared By

*Nance Gao*

( Nance Gao )  
Report Drafter

Authorized By

*Leo Liu*

( Leo Liu )  
Authorized Signatory

**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**

22-Jan-2021/ 22-Jan-2021

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

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

Sample Name: Disposable Vinyl Gloves  
Sample Specification: /  
Batch No./Date: /  
Manufacturer: Shandong Intco Medical Products Co., Ltd.

| SAMPLE NO. | DESCRIPTION | PHOTOGRAPH  |
|------------|-------------|---|
| 721661419  | Gloves      |  |

**TEST RESULT(S)**

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

- Specific migration of 22 Primary Aromatic Amine
  - Test method: With reference to EN 13130-1:2004, followed by LC/MS/MS
  - Test condition: 3% Acetic acid, 40°C for 0.5 hour
  - Migration ratio (S/V): 6dm<sup>2</sup>/L

| Test Item (s)                | CAS No.  | Result (s)<br>[mg/kg] | Maximum Permissible Limit<br>[mg/kg] |
|------------------------------|----------|-----------------------|--------------------------------------|
| 4-aminobiphenyl              | 92-67-1  | ND                    | 0.002                                |
| benzidine                    | 92-87-5  | ND                    | 0.002                                |
| 4-chloro-o-toluidine         | 95-69-2  | ND                    | 0.002                                |
| 2-naphthylamine              | 91-59-8  | ND                    | 0.002                                |
| o-aminoazotoluene            | 97-56-3  | ND                    | 0.002                                |
| 5-nitro-o-toluidine          | 99-55-8  | ND                    | 0.002                                |
| 4-chloroaniline              | 106-47-8 | ND                    | 0.002                                |
| 4-methoxy-m-phenylenediamine | 615-05-4 | ND                    | 0.002                                |
| 4,4'-diaminodiphenylmethane  | 101-77-9 | ND                    | 0.002                                |
| 3,3'-dichlorobenzidine       | 91-94-1  | ND                    | 0.002                                |
| 3,3'-dimethoxybenzidine      | 119-90-4 | ND                    | 0.002                                |
| 3,3'-dimethylbenzidine       | 119-93-7 | ND                    | 0.002                                |



|  |          |    |       |
|--|----------|----|-------|
| 4,4'-methylenedi-o-toluidine           | 838-88-0 | ND | 0.002 |
| p-cresidine                            | 120-71-8 | ND | 0.002 |
| 4,4'-methylene-bis- (2-chloro-aniline) | 101-14-4 | ND | 0.002 |
| 4,4'-oxydianiline                      | 101-80-4 | ND | 0.002 |
| 4,4'-thiodianiline                     | 139-65-1 | ND | 0.002 |
| o-toluidine                            | 95-53-4  | ND | 0.002 |
| 4-methyl-m-phenylenediamine            | 95-80-7  | ND | 0.002 |
| 2,4,5-trimethylaniline                 | 137-17-7 | ND | 0.002 |
| o-anisidine                            | 60-09-3  | ND | 0.002 |
| 4-amino azobenzene                     | 90-04-0  | ND | 0.002 |

Note: 1. ND denotes Not Detected and less than Detection Limit (Detection Limit=0.002mg/kg).

2. Specific migration of Heavy metals

- Test method: With reference to EN 13130-1:2004, followed by ICP-MS.
- Test condition: 3% Acetic acid, 40°C for 0.5 hour
- Migration ratio (S/V): 6dm<sup>2</sup>/L

| Test Item (s)   | Result (s)<br>[mg/kg] | Maximum Permissible Limit<br>[mg/kg] |
|-----------------|-----------------------|--------------------------------------|
| Lithium (Li)    | <0.1                  | 0.6                                  |
| Aluminium (Al)  | <0.1                  | 1                                    |
| Chromium (Cr)   | ND                    | ND (DL:0.01)                         |
| Manganese (Mn)  | <0.1                  | 0.6                                  |
| Iron (Fe)       | <5                    | 48                                   |
| Cobalt (Co)     | <0.01                 | 0.05                                 |
| Nickel (Ni)     | <0.01                 | 0.02                                 |
| Copper (Cu)     | <1                    | 5                                    |
| Zinc (Zn)       | <1                    | 5                                    |
| Arsenic (As)    | ND                    | ND (DL:0.01)                         |
| Cadmium (Cd)    | ND                    | ND (DL:0.002)                        |
| Antimony (Sb)   | <0.01                 | 0.04                                 |
| Barium (Ba)     | <0.1                  | 1                                    |
| Mercury (Hg)    | ND                    | ND (DL:0.01)                         |
| Lead (Pb)       | ND                    | ND (DL:0.01)                         |
| Lanthanum (La)  | <0.01                 | 0.05                                 |
| Europium (Eu)   | <0.01                 | 0.05                                 |
| Gadolinium (Gd) | <0.01                 | 0.05                                 |





|                         |       |      |
|-------------------------|-------|------|
| Terbium (Tb)            | <0.01 | 0.05 |
| Sum of [La, Eu, Gd, Tb] | <0.04 | 0.05 |

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

Note: 1. This report is for internal use only such as internal scientific research, education, quality control, product R&D.

-END OF THE TEST REPORT-

