Test Report No.: 721691875-1
Report Date: 11 June 2024

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	**Anhui Intco Medical Products Co., ltd**
CLIENT ADDRESS	No. 6, Haitang South Road, Suixi Wuhu Modern Industrial Park, Suixi County, Huaibei City, Anhui Province
TEST PERIOD	23-May-2024~04-Jun-2024

RESULT SUMMARY

1. The tested items **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.
   - Overall migration test **PASS**
   - Specific Migration of Total Primary Aromatic Amine **PASS**
   - Specific Migration of 22 Primary Aromatic Amine **PASS**
   - Specific Migration of Heavy metal **PASS**
   - Specific Migration of Vinyl Chloride **PASS**
   - Vinyl Chloride Monomer (VCM) content **PASS**
   - Specific Migration of Phthalates (DIBP, DBP, BBP, DEHP, DINP, DIDP, DAP, DEHA) **PASS**
   - Sensory test **PASS**
2. The tested items **complied with** France Law No. 2012-1442 of 24 December 2012 for the suspension of the manufacture, import, export and marketing of all-purpose food packaging containing bisphenol A
   - Bisphenol A content **PASS**

Prepared By	**Authorized By**
Minnie Gu	Anna Chi
(Minnie Gu) Report Drafter	(Anna Chi) 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.

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SAMPLE SOURCE/ RECEIPT DATE / TEST DATE

Logistics Express / 23-May-2024/ 23-May-2024

THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED BY/ ON BEHALF OF THE CLIENTS AS

Sample Name: Disposable Vinyl Gloves
Sample Type/ Specification: /
Batch No./Date: /
Manufacturer: /

SAMPLE NO.	DESCRIPTION	PHOTOGRAPH
721691875	Transparent glove	

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: With reference to EN 1186-3:2022
   - Migration ratio(S/V): 10dm^2/L

Simulant (s) Used	Test Condition	Result(s) [mg/dm^2]	Maximum Permissible Limit [mg/dm^2]
3% Acetic acid	40°C for 0.5 hour	<3.00	10
10% Ethanol	40°C for 0.5 hour	<3.00	10

2. Specific migration of Total Primary Aromatic Amine
   - Test method: With reference to EN13130-1:2004, followed by Kunststoffe im Lebensmittelverkehr, Book 2, Teil B II,XXI
   - Test condition: 3% Acetic acid, 40°C for 0.5 hour
   - Migration ratio(S/V): 6dm^2/L

Test Item(s)	Result(s) [mg/kg]	Maximum Permissible Limit [mg/kg]
Primary Aromatic Amine	<0.01	0.01

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3. 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): 6dm²/L

Test Item(s)	CAS No.	Result(s) [mg/kg]	Maximum Permissible Limit [mg/kg]
4-aminobiphenyl	92-67-1	ND	ND(DL:0.002)
benzidine	92-87-5	ND	ND(DL:0.002)
4-chloro-o-toluidine	95-69-2	ND	ND(DL:0.002)
2-naphthylamine	91-59-8	ND	ND(DL:0.002)
o-aminoazotoluene	97-56-3	ND	ND(DL:0.002)
5-nitro-o-toluidine	99-55-8	ND	ND(DL:0.002)
4-chloroaniline	106-47-8	ND	ND(DL:0.002)
4-methoxy-m-phenylenediamine	615-05-4	ND	ND(DL:0.002)
4,4'-diaminodiphenylmethane	101-77-9	ND	ND(DL:0.002)
3,3'-dichlorobenzidine	91-94-1	ND	ND(DL:0.002)
3,3'-dimethoxybenzidine	119-90-4	ND	ND(DL:0.002)
3,3'-dimethylbenzidine	119-93-7	ND	ND(DL:0.002)
4,4'-methylenedi-o-toluidine	838-88-0	ND	ND(DL:0.002)
p-cresidine	120-71-8	ND	ND(DL:0.002)
4,4'-methylene-bis- (2-chloro-aniline)	101-14-4	ND	ND(DL:0.002)
4,4'-oxydianiline	101-80-4	ND	ND(DL:0.002)
4,4'-thiodianiline	139-65-1	ND	ND(DL:0.002)
o-toluidine	95-53-4	ND	ND(DL:0.002)
4-methyl-m-phenylenediamine	95-80-7	ND	ND(DL:0.002)
2,4,5-trimethylaniline	137-17-7	ND	ND(DL:0.002)
o-anisidine	90-04-0	ND	ND(DL:0.002)
4-amino azobenzene	60-09-3	ND	ND(DL:0.002)

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

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4. Specific migration of Heavy metals
   - Test method: With reference to EN13130-1:2004, followed by ICP-MS.
   - Test condition: 3% Acetic acid, 40°C for 0.5 hour
     Migration ratio(S/V): 6dm²/L

Test Item(s)	Result(s) [mg/kg]	Maximum Permissible Limit [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.

5. Specific migration of Vinyl Chloride
   - Test method: With reference to EN13130-1:2004, followed by GC/MS
   - Test condition: 3% Acetic acid, 40°C for 0.5 hour
   - Migration ratio(S/V): 6dm²/L

Test Item(s)	Result(s) [mg/kg]	Maximum Permissible Limit [mg/kg]
Vinyl Chloride	ND	ND (DL:0.01)

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

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6. Vinyl Chloride Monomer (VCM) content
   - Test method: With reference to EN ISO 6401:2022 Plastics - Poly (vinyl chloride) - Determination of residual vinyl chloride monomer - Gas-chromatographic method

Test Item (s)	Result(s) [mg/kg]	Maximum Permissible Limit [mg/kg]
VCM	<0.1	1

7. Specific Migration of Phthalates
   - Test method: With reference to EN13130-1:2004, followed by GC/MS
   - Test condition: 3% Acetic acid, 40°C for 0.5 hour
   - Migration ratio(S/V): 6dm²/L

Test Item(s)	CAS No.	Result(s) [mg/kg]	Maximum Permissible Limit [mg/kg]
Diisobutyl phthalate (DIBP)	84-69-5	<0.05	--
Dibutyl Phthalate(DBP)	84-74-2	<0.05	0.12
Benzylbutyl Phthalate(BBP)	85-68-7	<0.05	6
Di(2-ethylhexyl) Phthalate(DEHP)	117-81-7	<0.05	0.6
Sum of (DBP, DIBP, BBP, DEHP), expressed as DEHP equivalents using the following equation: (DBP*5 + DIBP*4 + BBP*0.1 + DEHP*1)	--	<0.6	0.6
Diisononyl Phthalate(DINP)	28553-12-0	<0.50	Total 1.8
Diisodecyl Phthalate(DIDP)	26761-40-0	<0.50	
Diallyl phthalate(DAP)	131-17-9	ND	ND (DL:0.01)
Bis(2-ethylhexyl) adipate (DEHA)	103-23-1	<0.05	18

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

8. Sensory test
   - Test method: With reference to DIN 10955:2023-02.
   - Test condition: Distilled water, 40°C for 0.5 hour
   - Migration ratio(S/V): 1dm²/50ml

Sample(s)	Testing Parameter	Intensity result(s)	Description of the difference (from Intensity ≥ 2)	Recommended level
721691875	Transfer of look	0	NA	<3
	Transfer of taste	0	NA	<3
	Transfer of smell	0	NA	<3

Note: 1. NA denotes Not Applicable
2. Available Intensity scale are listed as follow:
Intensity scale: 0: No perceptible look/taste/smell deviation
1: Just perceptible look/taste/smell deviation
2: Weak look/taste/smell deviation
3: Clear look/taste/smell deviation
4: Strong look/taste/smell deviation

9. Bisphenol A content
   - Test method: With reference to in house method, analysed by LC/MS/MS

Test item(s)	Result(s) [mg/kg]	Maximum Permissible Limit [mg/kg]
Bisphenol A content	ND	Not Detected (DL:0.1)

Note: DL denotes Detection Limit, 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-

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