



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-Jun-2021~30-Jun-2021

RESULT SUMMARY

- 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; German Food & Feed Acts of September 1, 2005 (LFGB), Section 30 and 31; French Décret n° 2007-766 and its amendments, Arrêté du 5 août 2020 relating to rubber materials and objects intended to come into contact with foodstuffs and pacifiers for infants and young children; Article 3 of Regulation (EC) No. 1935/2004 (Materials and articles intended to come into contact with food); Staatscourant 2016 nr. 58058, of November 3rd, 2016
- Overall migration test **PASS**
- 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; Article 3 of Regulation (EC) No. 1935/2004 (Materials and articles intended to come into contact with food).
- Specific migration of Phthalates(BBP,DBP, DEHP, DINP, DIDP, DEHA, DAP) **PASS**
- Vinyl Chloride Monomer (VCM) content **PASS**
- Sensory test **PASS**
- 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**
- The tested items **complied with** European REGULATION (EU) 2019/1021 (amendment of 850/2004) on persistent organic pollutants.
- Short Chain of Chlorinated paraffin (C₁₀₋₁₃) (SCCP) content **PASS**

Prepared By

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Authorized 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

22-Jun-2021/ 22-Jun-2021

THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED

BY/ ON BEHALF OF THE CLIENTS AS

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

SAMPLE NO.	DESCRIPTION	PHOTOGRAPH
721664860	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: Part 5 (Test methods for overall migration into aqueous food stimulants by cell)
- Migration ratio(S/V): 10 dm²/L

Simulant(s) Used	Test Condition	Result(s) [mg/dm ²]	Maximum Permissible Limit [mg/dm ²]
3% Acetic acid	70°C for 2 hours	0.750	10
20% Ethanol	70°C for 2 hours	<0.500	10

Simulant(s) Used	Test Condition	Result(s) [mg/kg]	Maximum Permissible Limit [mg/kg]
3% Acetic acid	70°C for 2 hours	<5.00	60
20% Ethanol	70°C for 2 hours	<5.00	60





2. 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: 3% Acetic acid, 70°C for 2 hours
- Migration ratio(S/V): 6 dm²/L

Test Item(s)	CAS No.	Result(s) [mg/kg]	Maximum Permissible 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

3. Vinyl Chloride Monomer (VCM) content

- Test method: With reference to EN ISO 6401:2004 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

4. Sensory test

- Test method: With reference to DIN 10955
- The submitted sample was simulated in distilled water at 70°C for 2 hours. After this treatment treated water was examined by panels with regard to any divergence in smell and taste

Sample(s)	Testing Parameter	Grading result(s)	Recommended level
721664860	Transfer of taste	0	<3
	Transfer of smell	0	<3

- Note:
1. Available grading are listed as follow:

- Grading: 0: No perceptible taste/smell deviation
 1: Just perceptible taste/smell deviation
 2: Weak taste/smell deviation
 3: Clear taste/smell deviation
 4: Strong taste/smell deviation





5. Bisphenol A content

- Test method: In house method, analysed by LC/MS/MS

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

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

6. Short Chain of Chlorinated Paraffin (C10~13) (SCCP) Content

- Test method: In house method, solvent extraction by ultrasonic bath and determination by GC/ECD and GC-MS/NCI

Test Item(s)	Result(s) [%]	Maximum Permissible Limit* [%]
Short Chain of Chlorinated Paraffin(C ₁₀₋₁₃) (SCCP) Content	ND	0.15

Note: 1. ND denotes Not detected and less than detection limit (detection limit=0.01%)
2. * denotes the limit was quoted from (EU) 2019/1021 (amendment of 850/2004)

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

