



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

Lyncmed Medical Technology (Beijing) Co., Ltd

CLIENT ADDRESS

Room 119, Floor 1 GUOTOUSHANGKE Building No. 1111, South Huihe
Road Chaoyang District Beijing China

TEST PERIOD

23-Jan-2019~29-Jan-2019

TEST REQUEST

In accordance with DM/4B/COM/003 regarding the rules on synthetic material intended to come into contact with foodstuffs

- Overall migration test (10% Ethanol, 3% Acetic acid)
- Specific migration of Heavy metals
- Specific migration of Phthalates
- Residual Vinyl Chloride Monomer

RESULT SUMMARY

In accordance with DM/4B/COM/003 regarding the rules on synthetic material intended to come into contact with foodstuffs

- Overall migration test (10% Ethanol, 3% Acetic acid) **PASS**
- Specific migration of Heavy metals **PASS**
- Specific migration of Phthalates **PASS**
- Residual Vinyl Chloride Monomer **PASS**

Prepared By

Niki Xu

(Niki Xu)
Report Drafter



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. (5) The test result can be used by client for quality control.

RECEIPT DATE/ TEST DATE

23-Jan-2019/ 23-Jan-2019

THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED

BY/ ON BEHALF OF THE CLIENTS AS

Sample Name: PVC 手套
Sample Specification: S,M,L,XL
Batch No./Date: 2018-12-1
Manufactory: /

SAMPLE NO.	DESCRIPTION	PHOTOGRAPH
721643882	White glove	

TEST METHOD(S)

- For material: Plastics
 - Overall migration test in accordance with REGULATION (EU) No 10/2011 and its amendments on plastic materials and articles intended to come into contact with food.
 - As specified in REGULATION (EU) No 10/2011 and its amendments; with reference to EN 1186: Part 3 (Test methods for overall migration into aqueous food simulants by total immersion)
- Specific Migration: Heavy metal
 - Al, Ba, Co, Cu, Fe, Li, Mn, Zn, Ni
 - As specified in REGULATION (EU) No 10/2011 and its amendments, with reference to EN13130-1:2004, followed by ICP-MS.
- Specific migration of Phthalates
 - For compliance with REGULATION (EU) No 10/2011
 - With reference to EN 13130-1:2004, followed by GC-MS analysis.
- Residual Vinyl Chloride Monomer
 - With reference to ISO 6401:2008 Plastics - Poly(vinyl chloride) - Determination of residual vinyl chloride monomer - Gas-chromatographic method



TEST RESULT(S)

1. Overall Migration Test
- With reference to EN 1186: Part 3

Simulant(s) Used	Test Condition	Result(s) [mg/dm ²]	Maximum Permissible Limit [mg/dm ²]
10% Ethanol	40°C for 2 hours	2.6	10
3% Acetic acid	40°C for 2 hours	0.6	10

Note: 1. mg/dm² denotes milligram per square decimeter
2. Specification is quoted from (EU) No.10/2011

2. Specific Migration: Heavy metal - Al, Ba, Co, Cu, Fe, Li, Mn, Zn, Ni
- With reference to EN13130-1:2004, followed by ICP-MS.
- Test Condition: 3% acetic acid; 40°C for 2 hours

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

Note: 1. mg/kg denotes milligram per kilogram foodstuff
2. < denotes less than

3. Specific migration of Phthalates

- Test condition: Iso-octane , 20°C for 0.5 hour

Test Item(s)	CAS No.	MDL [mg/kg]	Test Result(s) [mg/kg]	Maximum Permissible Limit [mg/kg]
Benzylbutyl Phthalate(BBP)	85-68-7	0.25	<0.25	30
Dibutyl Phthalate(DBP)	84-74-2	0.2	<0.2	0.3
Di(2-ethylhexyl) Phthalate(DEHP)	117-81-7	0.25	<0.25	1.5
Diisononyl Phthalate(DINP)	68515-48-0	1.00	<1.00	9
Diisodecyl Phthalate(DIDP)	26761-40-0	1.00	<1.00	9
Diallyl phthalate(DAP)	131-17-9	0.01	<0.01	0.01
Bis(2-ethylhexyl) adipate(DEHA)	103-23-1	1.00	<1.00	18

Note: 1. mg/kg denotes milligram per kilogram foodstuff
2. < denotes less than
3. MDL denotes Method Detection Limit

4. Residual Vinyl Chloride Monomer - With reference to ISO 6401:2008

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

Note: 1. mg/kg denotes milligram per kilogram
2. < denotes less than

Notice: The samples pictured below have been confirmed by the customer to be of the same material as the sample tested



-END OF THE TEST REPORT-