



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 Changzhou universal medical equipment Co., Ltd

CLIENT ADDRESS No.6,Xinxi Road,XinbeiDistrict,ChangzhouCity,Jiangsu ProvinceThe peoples republic of China

TEST PERIOD 28-May-2021~08-Jun-2021

RESULT SUMMARY The tested items **complied with** German Food & Feed Acts of September 1, 2005 (LFGB), Section 30 and 31.

- Overall migration test (3% Acetic acid; 10% Ethanol, Water) **PASS**
- Specific migration of Primary Aromatic Amine **PASS**
- Color release **PASS**
- Extractable formaldehyde **PASS**
- Total lead and zinc content **PASS**
- Sensory test **PASS**
- Specific Migration of N-nitrosamines and N-nitrosatable substances **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

28-May-2021/ 28-May-2021

THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED

BY/ ON BEHALF OF THE CLIENTS AS

Sample Name: Disposable Powder Free Nitrile Gloves

Sample Specification: /

Batch No./Date: /

Manufactory: /

SAMPLE NO.	DESCRIPTION	PHOTOGRAPH
721664254	Blue glove	

TEST RESULT(S)

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

1. Overall Migration Test

- In accordance with BFR Recommendations XXI
- Test method: With reference to EN 1186: Part 5 (Test methods for overall migration into aqueous food stimulants by cell) and BFR Recommendations XXI
- Migration ratio (S/V): 10dm²/L

Simulant(s) Used	Test Condition	Result(s) [mg/dm ²]	Maximum Permissible Limit [mg/dm ²]
3% Acetic acid	40°C for 10 minutes	3.45	10
10% Ethanol	40°C for 10 minutes	<0.500	10
Water	40°C for 10 minutes	<0.500	10

2. Specific migration of 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 10 minutes
- Migration ratio (S/V): 6dm²/L

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





3. Color release

- Test method: With reference to Kunststoffe im Lebensmittelverkehr Book II, Teil B II, IX

Simulant(s) Used	Test Condition	Result(s)	Permissible Limit
10% Ethanol	50°C for 5 hours	No bleeding	No bleeding
2% Acitic acid	50°C for 5 hours	No bleeding	No bleeding
Peanut oil	50°C for 5 hours	No bleeding	No bleeding
Water	50°C for 5 hours	No bleeding	No bleeding

Note: 1. No bleeding denotes no difference was found between blank and sample
2. Bleeding denotes staining was found from sample

4. Extractable formaldehyde

- Test method: For compliance with the Recommendation of the BfR "Kunststoffe im Lebensmittelverkehr" Part XXI. Commodities based on Natural and Synthetic Rubber
- With reference to Section 2.7.1 of methods for the "Testing of commodities made of rubber"
- Test condition: 3% Acetic acid, 40°C for 10 minutes
- Migration ratio (S/V): 6dm²/L

Test Item(s)	Result(s) [µg/ml]	Maximum Permissible Limit [µg/ml]
Extractable Formaldehyde	<0.5	3

5. Total lead and zinc content

- Test method: Acid digestion, then followed by ICP-OES

Test Item(s)	Result(s) [%]	Maximum Permissible Limit [%]
Lead content	<0.001	0.003
Zinc content	0.8452	3.0

6. Sensory test

- Test method: With reference to DIN 10955.

- The submitted sample was simulated in distilled water at 40°C for 10 minutes. 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
721664254	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



7. Specific Migration of N-nitrosamines and N-nitrosatable substances

- Test method: Sample preparation with reference to EN 12868:2017, followed by analysis using LC-MS-MS
- Test condition: 3% Acetic acid, 40°C for 10 minutes

Test Item(s)	Result(s) [µg/dm ²]	Detected limit [µg/dm ²]	Maximum Permissible Limit [µg/dm ²]
N-nitrosamines	ND	1	1.0

Test Item(s)	Result(s) [mg/kg]	Detected limit [mg/kg]	Maximum Permissible Limit [mg/kg]
N-nitrosatable substances	ND	0.1	0.1

- Note: 1. ND denotes not detected and less than Detected limit
2. Tested N-nitrosamines are listed below:

	Compounds name	Abbreviation	CAS#
1	N-Nitrosodimethylamine	NDMA	62-75-9
2	N-nitrosodiethylamine	NDEA	55-18-5
3/4	N-nitrosopyrrolidine or N-nitroso N-methyl N-phenylamine	NPYR or NMPPhA	930-55-2 or 614-00-6
5	N-nitrosomorpholine	NMOR	59-89-2
6	N-Nitrosodi-n-propylamine	NDPA	621-64-7
7	N-nitrosopiperidine	NPIP	100-75-4
8	N-nitroso N-ethyl N-phenylamine	NEPhA	612-64-6
9	N-Nitrosodi-n-butylamine	NDBA	924-16-3
10	N-nitrosodibenzylamine	NDBzA	5336-53-8
11	N-Nitrosodiisononylamine	NDiNA	1207995-62
12	N-nitrosomethylethylamine	NMEA	10595-95-6
13	N-nitrosodiisobutylamine	NDiBA	997-95-5

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

-END OF THE TEST REPORT-