Test Report No.: 721670365-1
Report Date: 17 February 2022

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	**Zhonghong Pulin Medical Products Co., Ltd.**
CLIENT ADDRESS	West Industrial Park, BDA, Luannan, Tangshan, 063500 Hebie, P.R. China
TEST PERIOD	29-Jan-2022~16-Feb-2022
RESULT SUMMARY	The tested items **complied with** European Resolution Res AP (2004) 4 on rubber products intended to come into contact with foodstuffs. - Overall migration test **PASS** - Specific Migration of Total Primary Aromatic Amine **PASS** - Specific Migration of N-nitrosamines and N-nitrosatable substances **PASS**

Prepared By

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(Wei Jun)
Report Drafter

Authorized By

Lee Liu

(Lee 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.

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No.151 Heng Tong Road Shanghai
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RECEIPT DATE / TEST DATE

29-Jan-2022/ 29-Jan-2022

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

Sample Name: Powder free nitrile glove,blue
Sample Specification: M
Batch No./Date: 2022.1.25
Manufacturer: /

SAMPLE NO.	DESCRIPTION	PHOTOGRAPH
721670365	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
   - Test method: With reference to EN 1186-4:2002/ EN 1186-5:2002/ EN 1186-14:2002
   - Migration ratio(S/V): 10dm²/L

Simulant(s) Used	Test Condition	Result(s) [mg/kg]	Maximum Permissible Limit [mg/kg]
3% Acetic acid	40°C for 30 minutes	18.9	60
10% Ethanol	40°C for 30 minutes	<5.0	60
95% Ethanol	40°C for 30 minutes	26.7	60
Iso-octane	20°C for 6 minutes	<5.0	60

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 30 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

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3. Specific migration of N-nitrosamines and N-nitrosatable substances
   - Test method: With reference to EN 12868:2017, followed by analysis using LC-MS-MS
   - Test condition: 3% Acetic acid, 40°C for 30 minutes

Test Item(s)	Result(s) [mg/kg]	LOD [mg/kg]	Maximum Permissible Limit [mg/kg]
N-nitrosamines	ND	0.001	0.01
N-nitrosatable substances	ND	0.01	0.1

Note: 1. ND denotes not detected and less than LOD(LOD denotes limit of detection)
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 NMPhA	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	1207995-62-7
12	N-nitrosomethlethylamine	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-

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