



# Test Report

Report No : TST202111Q3177-6EN Date:Nov.22, 2021

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**Applicant/**

Anhui Intco Medical Products Co.,Ltd.

**Manufacturer:**

**Address:**

No. 6, Haitang South Road, Suixi Wuhu Modern Industrial Park, Suixi County,  
Huaibei City, Anhui Province ,China

The following sample(s) was /were submitted and identified on behalf of the clients as :

**Sample Name:** Disposable Nitrile Gloves (NBR)

**Sample Model:** XS/S/M/L/XL/XXL

**Sample Received Date:** Nov.19, 2021

**Testing Period:** Nov.19, 2021 To Nov.22, 2021

**Test Requested:** In accordance with European Commission Directive 1935/2004/EC, Regulation (EU) No.10/2011,Regulation (EU) 2016/1416 and Regulation (EU) No. 2017/752, Regulation (EU) 2018/213 and Regulation (EU) 2018/831 Regulation (EU) 2020/1245 on plastic materials and articles intended to come into contact with food ,In accordance with Italian Official Gazette (G.U.) DMH 21 March1973 , GU Decree of the Ministry of Health No. 220 of 26-4-1993 and 2002/72/EC.

**Test Method:** Please refer to next page(s).

**Test Result:** Please refer to next page(s).

Signed for and on behalf of



**Andy Zheng**  
**Technical Director**

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## Sample Description:

No.	Sample Description
1	Disposable Nitrile Gloves (NBR)

## Test Result(s):

### 1.1 Overall migration

Method: Refer to EN1186:2002

Material	Test Condition	Limit (mg/dm <sup>2</sup> )	Result(mg/dm <sup>2</sup> )			Conclusion
			1st	2nd	3rd	
No.1	20% Ethanol(v/v),40°C,2 hours	10	<3	<3	<3	PASS
	3% Acetic acid(w/v), 40°C,0.5 hours	10	<3	<3	<3	PASS
	Olive oil, 40°C,2 hours	10	<3	<3	<3	PASS

- Note:**
- 1.mg/dm<sup>2</sup> = milligram per square decimetre of surface area of material or article.
  - 2.mg/kg = milligrams of the constituents released per kilogram of foodstuff.
  - 3.The requirement in accordance with the Commission Regulation(EU) 2020/1245

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## 1.2 Primary aromatic amines

Method: Refer to EN 13130-1:2004, was analyzed by GCMS.

No.	Name	CAS No.	Result	MDL
1	4-Aninobiphenyl	92-67-1	N.D.	0.002
2	4-Chloro-o-toluidine	95-69-2	N.D.	0.002
3	2-Naphthylamine	91-59-8	N.D.	0.002
4	o-Aminoazotoluene	97-56-3	N.D.	0.002
5	2-Amino-4-nitrotoluene	99-55-8	N.D.	0.002
6	p-Chloroaniline	106-47-8	N.D.	0.002
7	2,4-Diaminoanisole	615-05-4	N.D.	0.002
8	4,4'-Diaminobiphenylmethane	101-77-9	N.D.	0.002
9	3,3'-Dichlorobenzidine	91-94-1	N.D.	0.002
10	3,3'-Dmethoxybenzidine	119-90-4	N.D.	0.002
11	3,3'-Dimethylbenzidine	119-93-7	N.D.	0.002
12	3,3'-Dimethyl-4,4-diaminobiphenylmethane	838-88-0	N.D.	0.002
13	p-Cresidine	120-71-8	N.D.	0.002
14	4,4'-Methylene-bis- (2-chloroaniline)	101-214-4	N.D.	0.002
15	4,4'-Oxydianiline	101-80-4	N.D.	0.002
16	4,4'-Thiodianiline	139-65-1	N.D.	0.002
17	o-Toluidine	95-53-4	N.D.	0.002
18	2,4-Toluylendiamine	95-80-7	N.D.	0.002
19	2,4,5-Trimethylaniline	137-17-7	N.D.	0.002
20	o-Anisidine	90-04-0	N.D.	0.002
21	2,4-Xylidine	95-68-1	N.D.	0.002
22	2,6-Xylidine	87-62-7	N.D.	0.002
	Sum of PAAs	-	N.D.	0.01

Note:

1. mg/kg=ppm
2. N.D. = Not Detected (<MDL)
3. MDL = Method Detection Limit

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## 1.3 Formaldehyde Special Migration Test

Simulant used	Test condition	Overall Migration (mg/kg)	Maximum permissible Limit (mg/kg)
20% Ethanol	2 h at 40°C	<2.0	15
3% Acetic acid	0.5 h at 40°C	<2.0	15
Olive oil, 40°C	2 h at 40°C	<2.0	15

## 1.4 N-nitrosamines and N-nitrosatable substances

Method: With reference to EN 12868-1999, analyzed by Gas Chromatograph-Mass Spectrometry (GC-MS).

Test Item	Limit (mg/kg)	Result (mg/kg)	Conclusion
N-nitrosamines	0.01	N.D.	PASS
N-nitrosatable substances	0.1	N.D.	PASS

Note: mg/kg = milligram per kilogram (ppm).

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## 1.5 Color migration test (EN646:2006)

Sample Description	Simulant Used	Test condition	Detection Result
Disposable Nitrile Gloves (NBR)	3% Acetic Acid (W/V) Aqueous Solution	40°C,0.5 hours	5 Grade
	Saliva simulator	40°C,2 hours	
	Rectifying olive oil	40°C,2 hours	

Remarks: Gray scale is based on level 1-5, level 1 is the worst and level 5 is the best

## 1.6 Phthalate test

**Total Phthalate Method:** Refer to EN 13130-1:2004,was analyzed by GCMS.

Test Item(s)	Unit	Result	MDL	Limit
Dibutyl Phthalate(DBP)	mg/kg	N.D.	30	500
Benzylbutyl Phthalate (BBP)	mg/kg	N.D.	30	1000
Di-(2-ethylhexyl) Phthalate(DEHP)	mg/kg	N.D.	30	1000
Diisononyl Phthalate(DINP)	mg/kg	N.D.	100	1000
Di-n-octyl Phthalate(DNOP)	mg/kg	N.D.	30	1000
Diisodecyl Phthalate (DIDP)	mg/kg	N.D.	100	1000
Bis(2-ethylhexyl) adipate (DEHA)	mg/kg	N.D.	100	--
Diocetyl terephthalate (DEHTP)	mg/kg	N.D.	100	--

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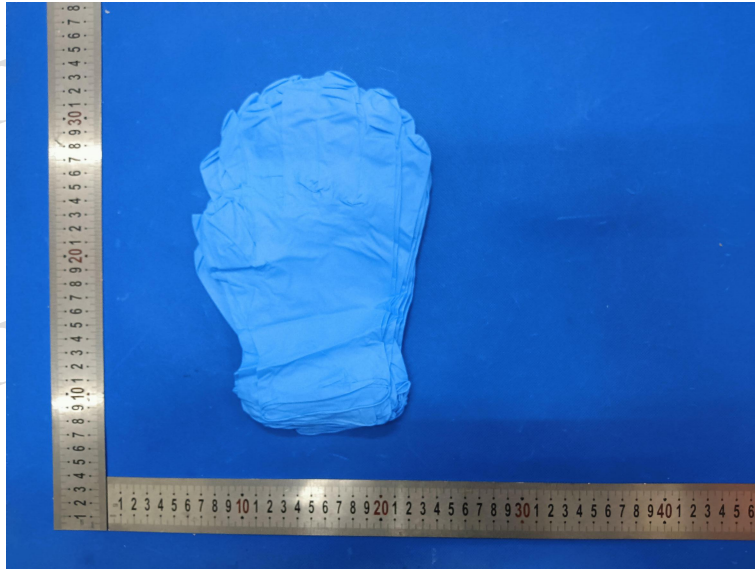
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## Sample photo:



\*\*\* End of Report \*\*\*

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