Český překlad některých podstatných údajů.

TEST REPORT : modré nitrilové rukavice

Report No.: S210605457_1 21 June 2021 <u>APPLICANT</u>: S I NOA00 MEDICAL CORP (C42040)

The report is issued by CTC Shanghai under its General Conditions printed overleaf. The results shown in this report refer only to the sample (s) tested.

Except by special arrangement, the test items will not be retained by CTC Shanghai for more than 3 months. The test report shall not be reproduced, except in full, without the written approval of the testing laboratory.

To declare the conformity to the requirement, the uncertainty of measurement, associated to the test results, has not been taken into account.

Report vydaný CTS Shanghai dle jeho všeobecných podmínek a týká se pouze testovaných vzorků. Kromě spec.podmínek, testované položky si CTC Shaghai ponechá Déle než 3 měsíce. Výsledek testu je možné reprodukovat pouze vcelku bez jakýchkoli písemných doplnění. Pro deklaraci shody s požadavky neurčitá měření nebyla brána v úvahu.

Bylo posuzováno: Test 210605457 -1

Dle ISO 21420/EN ISO 374-1

Celá rukavice

ISO 214-2:2020 dexterity/zručnost

ISO 374-2: 2019 tlouštka, test natlakování a test vodopropustnosti

ISO 3071: 2020 pH hodnota

ISO 14362-1: 2017 aromatické aminy

ISO/TS 16190:2013 polycyklické aromatické hydrokarbonáty

ASTMF2617-15 cadmium a cín screening

CEN ISO TS 16181:2011 ftaláty

Výsledky byly v normě = prošel

Test byl proveden externí aktreditovanou laboratoří dle akreditačního rámce. Pokud není specifikováno jinak, tato expertíza se prováděla v CTC Shanghai lab za podmínek T 23+- 2°C/RH 50+-4%

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Odborný garant Ing. Kamila Bořecká



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TEST REPORT

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21 June 2021

APPLICANT: SINOAOO MEDICAL CORP (C42040)

ROOM 1310, BUILDING 1, WINDOW OF GREEN SPACE BUSINESS PLAZA, JINYUAN ROAD 2, DONGSHAN STREET JIANGNING

NANJING JIANGSU

CHINA

Date of receipt :10 June 2021 :15 June 2021 Testing period

:18 June 2021

Karen. yu@labtesting.cn

Buyer: --

DISPOSABLE NITRILE GLOVE Sample description:

Style / Article no. :SANG002

Test(s) requested For CE Marking: Yes Previous report : REGULAR Service Product category Brand / Section Product type Season

:FIRST TEST Test stage End use

Factory name Supplier name

Exported to : 欧盟/EU Factory code

1. Conclusion:

	Tests description	<u>Conformity</u>
	EN ISO 21420/EN ISO 374-1	
1	pH - Textile (KCI solution)	Pass
2	Aromatic amines derived from azo colorants	Pass
3	Polycyclic Aromatic Hydrocarbons (8)	Pass
4	Dexterity	Level 5
5	Air Leak Test	Pass
6	Water Leak Test	Pass
7	Dimethylfumarate (DMFu)	Pass
8	XRF screening	Pass
9	XRF screening (Tin)	Pass
10	Phthalates	Pass

Pass: requirements met Fail: requirements not met None: no requirement for this test N/A: not applicable







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21 June 2021

APPLICANT: SINOAOO MEDICAL CORP (C42040)

Approved by

Henry YAN 严滨

Laboratory Manager

Yvonne MAO 茅璇怡

Senior Analytical Chemical Engineer







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APPLICANT: SINOAOO MEDICAL CORP (C42040)

2. Sample(s) description assigned by laboratory:

Size	Analyzed product	<u>Description</u>	Sample information				
	GLOVE						
	Whole glove						
blue nitrile palm/back							



210605457







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21 June 2021

APPLICANT: SINOAOO MEDICAL CORP (C42040)

3. GLOVE/

Whole glove

	Method	Client Requirement	Unit	Result	Conformity
(+) 5.2. Dexterity	EN ISO 21420: 2020				
Smallest diameter of pin fulfilling test condition			mm	5.0	
Smallest diameter of pin fulfilling test condition (2)			mm	5.0	
Smallest diameter of pin fulfilling test condition (3)			mm	5.0	
Smallest diameter of pin fulfilling test condition (4)			mm	5.0	
Performance level				5	
Air Leak Test	EN ISO 374-2:2019				Pass
Glove thickness			mm	0.09	
Air pressure used to test			kPa	2.3	
Result		No air bubbles		No air bubbles	
Water Leak Test	EN ISO 374-2:2019				Pass
Result		No water leak		No water leak	

blue nitrile palm/back

	Method	Client Requirement	Unit	Result	Conformity
(+) 4.2. pH - Textile (KCI solution)	ISO 3071:2020				Pass
pH value		3.5< - <9.5		6.9	
4.2. Aromatic amines derived from azo colorants	ISO 14362-1:2017 (w/o extraction)				Pass
Accessible without fibre extraction		<30	mg/kg	<5	
▲ 4.2. Polycyclic Aromatic Hydrocarbons (8)	ISO/TS 16190: 2013				Pass
Benzo(a)anthracene		<1	mg/kg	<0.1	
Chrysene		<1	mg/kg	<0.1	
Benzo(b)fluoranthene		<1	mg/kg	<0.1	
Benzo(k)fluoranthene		<1	mg/kg	<0.1	
Benzo(a)pyrene		<1	mg/kg	<0.1	
Dibenzo(a.h)anthracene		<1	mg/kg	<0.1	
Benzo(e)pyrene		<1	mg/kg	<0.1	

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APPLICANT: SINOAOO MEDICAL CORP (C42040)

	Method	Client	Unit	Result	Conformity
		Requirement			
Benzo(j)fluoranthene		<1	mg/kg	<0.1	
▲ Dimethylfumarate (DMFu)	ISO/TS 16186 : 2012				Pass
Dimethylfumarate		<0.1	mg/kg	<0.1	
(+) XRF screening	ASTM F2617 – 15				Pass
Cd (Cadmium)		<100	ppm	<100	
XRF screening (Tin)	ASTM F2617 – 15				Pass
Sn (Tin)		<150	ppm	<150	
Phthalates	CEN ISO TS 16181 : 2011				Pass
BBP . Butyl benzyl phthalate		<0.1	%	<0.0025	
DBP . Di-butyl phthalate		<0.1	%	<0.0025	
DEHP . Di-(2-ethylhexyl) phthalate		<0.1	%	<0.0025	
DIBP . Di-iso-butyl phthalate		<0.1	%	<0.0025	

END OF TEST REPORT

(+)CNAS accreditation

- ▲: The test was carried out by external accredited laboratory under their accreditation scope.
- •: The test was carried out by external accredited laboratory, not within their accreditation scope.

Unless otherwise specified, the physical test items in this report performed in CTC Shanghai lab were conditioned and tested in the environment of T 23±2°C / RH 50±4%.

Table of Performance Level for Glove

Test Item	Performance Level						
1001110111	0##	1	2	3	4	5	
Finger dexterity (EN ISO 21420) Smallest diameter of pin fulfilling test conditions (mm)		11.0	9.5	8.0	6.5	5.0	

Performance level 0 means the glove falls below the minimum performance level for the given individual hazard