

EN ISO 374-2 Zertifikat für sunaMed Nitril Handschuhe

sunaMed Dokumenten Nummer:

sunamed1006

Aktuelle Version:

Auflage 1 Erstellt am: 10.9.2021

Mit Erscheinen dieser Version verlieren alle vorigen Versionen ihre Gültigkeit.

Gültig für nachfolgende Artikelnummern:

Gr.	EAN	Art Nr.		Artikel
S	4260274354544	1080	100 Handschuhe S blau Nitril MDR1 noP sunaMED	100 Exam gloves S blue nitrile MDR1 noP sunaMED
M	4260274354551	1081	100 Handschuhe M blau Nitril MDR1 noP sunaMED	100 Exam gloves M blue nitrile MDR1 noP sunaMED
L	4260274354568	1082	100 Handschuhe L blau Nitril MDR1 noP sunaMED	100 Exam gloves L blue nitrile MDR1 noP sunaMED
XL	4260274354575	1083	100 Handschuhe XL blau Nitril MDR1 noP sunaMED	100 Exam gloves XL blue nitrile MDR1 noP sunaMED

Abkürzungen:

MDR1 = MDR Klasse 1 noP = no Powder



EN ISO 374-2 Zertifikat



SATRA Technology Services (Dongguan) Ltd Unit 110, Xirzhongyin Garden, Xiping Nancheng District, Dongguan City Guangdong Province, China Tel: +96 (0) 769 2288020 email: into@satrate.com

Customer details: Guangzhou Junda Gloves Co., Ltd

38 Feng Wei Industrial Area, Heting Renhe Town, Baiyun District

Guanazhou Guangdong China SATRA reference: CHT0298845 /2023/

Issue 2

DQ1003 (L), DQ1002 (M), DQ1001 (S) Your reference:

4 September 2020

Date of report:

Samples received: 6 June 2020

Date(s) work

15 June 2020 to 30 June 2020

TECHNICAL REPORT

(This report replaces the technical report of CHT0298845 /2023 issued on 1 July 2020)

Subject:

EN ISO 21420: 2020 size & dexterity, pH and PAHs test, EN 374-2: 2014 air leak and water leak on Disposable Nitrile Gloves, referenced as DQ1003 (L), DQ1002 (M), DQ1001 (S), Colour: Blue, size: 6/S, 7/M, 8/L.

This report may be forwarded to other parties provided that it is not changed in any way. It must not be published, for example by including it in advertisements, without the prior, written permission of SATRA.

Results given in this report refer only to the samples submitted for analysis and tested by SATRA. Comments are for guidance only.

A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested. SATRA shall not be liable for any subsequent loss or damage incurred by the client as a result of information supplied in the report.

The uncertainty of the results (UoM) in this report is based on a standard uncertainty multiplied by a coverage factor k=2, which provides a coverage probability of approximately 95%.

Report signed by:

Adam Zhang

Department:

Technologist China Testing

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Adam Zhang





WORK REQUESTED

Samples described as Disposable Nitrile Gloves, referenced as DQ1003 (L), DQ1002 (M), DQ1001 (S), Colour: Blue, size: 6/S, 7/M, 8/L were received by SATRA on 6 June 2020 for testing in accordance with EN ISO 21420: 2020 and EN 374-2: 2014.

SAMPLE SUBMITTED



Samples described as Disposable Nitrile Gloves, referenced as DQ1003 (L), DQ1002 (M), DQ1001 (S), Colour: Blue, size: 6/S, 7/M, 8/L

TESTING REQUESTED

EN ISO 21420: 2020 Clause 5.1 - Sizing and measurement of gloves

EN ISO 21420: 2020 Clause 5.2 - Dexterity

EN ISO 21420: 2020 Clause 4.2 - Innocuousness of protective gloves

EN 374-2: 2014 Clause 7.2 - Air leak

EN 374-2: 2014 Clause 7.3 - Water leak

CONCLUSION

The samples described as Disposable Nitrile Gloves, referenced as DQ1003 (L), DQ1002 (M), DQ1001 (S), Colour: Blue, size: 6/S, 7/M, 8/L were found to achieve the following results:

EN ISO 21420: 2020 Clause 5.1 - See below table

EN ISO 21420: 2020 Clause 5.2 - Level 5

EN ISO 21420: 2020 Clause 4.2* - Pass PAHs and pH value

EN 374-2: 2014 Clause 7.2* - Pass

EN 374-2: 2014 Clause 7.3* - Pass

All tests marked * in this technical report were subcontracted to test facilities accredited to ISO/IEC 17025: 2017 by CNAS.

Detailed results are included on the following page(s)

Guangzhou Junda Gloves Co., Ltd

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Signed:

Adam Zhaner have Pechnologist China Testing

SUNASAR AG +41 31 506 10 67 Bergblickweg 3 prz@sunamed.ch

CH-6060 Sarnen www.sunamed.ch





Testing

Testing was carried out in accordance with EN ISO 21420: 2020

Samples for testing were conditioned for at least 24 hours in a conditioned environment maintained at (23 \pm 2) °C and (50 \pm 5) % relative humidity.

Requirements

Table 1 - Requirements for EN ISO 21420: 2020 Clause 5.2 Dexterity

Performance level	1	2	3	4	5
Diameter of dexterity pin /mm	11.0	9.5	8.0	6.5	5.0

Test Results

Table 2 - EN ISO 21420:2020 Test Results.

Clause / Test	Requirement	Т	est Resu	ults		UoM (See note ♣)	Result
		Length /mm					
	N/A	Size	1	2	3		
200		0160	228	231	235	1- 200	25
5.1 Glove		Comfortable on fit				200	NIA
length, comfort and fit		7	237	240	241	± 1.10 mm	N/A
STEP	MBC	Comfortable on fit				EP 1002	LEP
MBL	OLFINOC	820	245	243	245	PRICE	MAL
TEL SE	200	Comfortable on fit				Br, OLL	200
200	ELLEN	Size	Minimu	m pin diame	eter / mm	0200	1000
5.2 Dexterity	erity See table 1	60	6 5.0		N/A	Level 5	
		7	5.0		IN/A	Level 5	
	BELL	8 5	000	5.0	701	CL V SP	200

Additional Information / Notes

Note • – Estimated uncertainty of measurement applied at point of test (e.g. to applied force or to tolerance limits) to ensure product meets requirements of the standard.

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Innocuousness Testing

RESULTS:

Sample Item	Sample Description	Location	Style
1001	Blue soft plastic	Gloves	/ \ - \

pH Value-EN ISO 21420:2020

Test Method I: With reference to ISO 4045:2008, analyzed by pH meter. Test Method II: With reference to ISO 3071:2005, analyzed by pH meter.

Requirement:	3.5-9.5
riequirement.	0.0-9.0

-	Unit	Result					
Test Item(s)	n(s) - 1001						
Test Method	-	II					
Parameter	-	-					
pH Value of Extracting Solution	-	5.36					
Temp. of Aqueous Extract	deg. C	25.1					
pH Value of Aqueous Extract	-	7.1					
Difference Figure							
Conclusion	CK.	PASS					

Note / Key: deg. C = degree Celsius (°C) Temp. = Temperature Remark: Result(s) was (were) reported the average value from two trials.

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RESULTS:

Polycyclic Aromatic Hydrocarbons (PAHs) Content –European Parliament and Council Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Annex XVII with its Latest Amendment, Entry 50, point 5

Test Method: With reference to test method mentioned in German AfPS GS 2014:01 PAK.

Maximum Allowable Limit:	Each of all listed PAHs: 1.0 mg/kg ^[e]

Tested Item(s)	F	O-malualan		
	Detected Analyte(s)	Conc.	Unit	Conclusion
1001	ND	ND	mg/kg	PASS

Note / Key: ND = Not detected(<Detection Limit) Detection Limit (mg/kg): Each: 0.2;

mg/kg = milligram per kilogram = ppm = part per million

Remark: The list of polycyclic aromatic hyrdocarbons is summarized in table of Appendix.

[a]denotes as this maximum allowable limit applies to product(s) placed on the market for the first time on or

after December 27, 2015 only.

Rubber or plastic component(s) of articles that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity under normal or reasonably foreseeable conditions of use is (are) applicable to be tested. Such articles include amongst others:

- sport equipment such as bicycles, golf clubs, racquets

- household utensils, trolleys, walking frames

- tools for domestic use

clothing, footwear, gloves and sportswear

- watch-straps, wrist-bands, masks, head-bands

APPENDIX List of Polynuclear Aromatic Hydrocarbons:							
No.	Name of Analytes	CAS-No.	No.	Name of Analytes	CAS-No.		
1	Chrysene	218-01-9	5	Dibenzo (a,h) anthracene	53-70-3		
2	Benzo (a) pyrene	50-32-8	6	Benzo (b) fluoranthene	205-99-2		
3	Benzo (e) pyrene	192-97-2	7	Benzo (j) fluoranthene	205-82-3		
4	Benzo (a) anthracene	56-55-3	8	Benzo (k) fluoranthene	207-08-9		

Guangzhou Junda Gloves Co., Ltd

SATRA Reference: CHT029884

Date: 4 September 2020

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TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

- 1.2 SATRA Technology Services (Dongquan) Limited (朱亮基章校测技术服务有股公司), its subsidiaries and associated companies (hereinatter referred to as "SATRA") may perform Services for, or supply Goods to persons or entities (public, private or governmental) issuing instructions (hereinatter termed the "Client"). Each also known individually as a Party, or jointly as Parties.

- - "Contract" is the contract between SATRA and the Client for the supply of Goods or Services which is made subject to these terms and conditions; and
 - "Services' are the work or services to be supplied or performed under the Contract (including, where relevant the supply of software, components and consumables); and
 - "Goods" are the equipment, consumables or other physical items sold under the Contract (including documents, drawings or other information required in order to operate the equipment)
 - 1.5.4 "PRC" means the People's Republic of China.
- All drawings, descriptive matter, specifications and advertising material (including brochures and catalogues) are issued or published with the sole purpose of giving an indication of the Goods or Services being described and shall not form part of the Contract.

- 2.5 Quotations are valid from the date of issue for a period of 90 days unless otherwise sp
- 2.7 All invoices issued by SATPA are payable in full. The Client is responsible for payment of within other taxes and all import duties. Payments made to SATPA shall not be reduced by such amo
- 2.8 The Client shall not be entitled to withhold or defer payment due to SATRA as a result of any counter claim that it may allege against SATRA.

- SUSPENSION OR TERMINATION OF SERVICES

- 5.2 Nothing in these terms and conditions shall limit or exclude SATRA's liability for
 - death or personal injury caused by its negligence or the negligence of its of fraud or fraudulent misrepresentation; or any other liability which cannot be limited or excluded by applicable law.
- Subject to clause 5.2 SATRA's total aggregate liability to the Client, whether in contract, tort negigence), breach of statutory duty or otherwise arising under or in connection with the Contract limited to the total amount of fees for the Seories or the price of the Scode (secular) any value and other sales tax or expenses) payable by the Client to SATRA under the Contract or RMB500,000 with lower figure.

MISCELLANEOUS

- 6.6 To the extent permitted by applicable laws and regulations, all provisions of the Contract that limit or exclude the liability of SATRA are intended also to be for the benefit of SATRA's holding company (talled SATRA, and being a company limited by guarantee and incorporated in England and Walse with company number 0.0153475), and shall accordingly be endirecable by such nothing company as well as or instead of by SATRA, and on the basis that any limit on the slability of SATRA shall apply of a and to such holding company in the

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Adam Thang Zhang Technologist

China Testing

SUNASAR AG +41 31 506 10 67 Bergblickweg 3 prz@sunamed.ch CH-6060 Sarnen www.sunamed.ch

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TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

10 PROVISION OF SERVICES

- 10.2 Estimates for completion of the Services are made in good faith and date from receipt of a written order, payment of a proforma invoice if required, full information and samples to enable SATRA to proceed. While SATRA will make every effort to fulf them, such estimates are subject to unfortenese events and if not achieved, cannot give rise to any claim. Time will not be of the essence in relation to the performance of the
- 10.3 Results given in test reports or certificates refer only to samples submitted for analysis to SATRA satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty given as to the performance of the product tested.
- 10.4 SATRA may delegate all or part of the Services to a subcontractor and the Client authorises SATRA to disclose all information required to undertake the Services.
- 10.5 Where the Client requests SATRA to whose stating of other services being undertaken by a third party the Client agrees that SATRAs is one reportability in to be present at the time of the work and to feverable the results or confirm that the service has been undertaken. The Client agrees that unless otherwise agreed SATRA in or responsible for the confirm or adaption of any experiment unless provided by SATRA.
- 10.6 Unless otherwise agreed in advance, test samples will be retained for 6 weeks from the date of the final report after which time they will be disposed of and SATPA shall cease to have any responsibility for such samples.

Where the nature of the samples or the Services undertaken results in specialist disposal then SATRA reserves the right to pass the cost of such disposal onto the Client.

Storage for longer periods may be possible only if agreed in advance and may incur a storage charge publy the Client.

- 10.9 The Client acknowledges that SATRA by providing the Services, neither takes the place of the Client third party or releases them from any of their obligations.
- 11 CLIENT RESPONSIBILITIES RELATING TO THE PROVISION OF SERVICES
- 11.1 The Client shall provide sufficient samples, information, instructions and documents as required to enable SATRA to carry out the Services in accordance with the methods, standards or other specifications as agreed.
- 11.2 Where applicable the Client shall allow access by members of SATRA staff to such premises where the Services are to be performed and provide any specialist equipment and personnel.
- 11.3 The Client shall inform SATRA in advance of any known hazards, dangers or other safety matters relating to samples submitted to SATRA or on site visits made by SATRA.
- 11.4 Where the Client fails to comply with any of its responsibilities SATRA reserves the right to suspend any Services until such time as the Client has compiled and may require the Client to reimburse SATRA the sequented any additional costs arising from the supervision.
- 12 DELIVERY AND NON-DELIVERY OF GOODS
- 12.1 Delivery dates for the supply of the Goods are approximate only and not guaranteed. Time of delivery is not of the essence of the Contract and SATRA shall not be liable for any delay in delivery of Goods.
- 12.2 Should expedited delivery be requested and agreed, SATRA shall be entitled to make additional charges to cover overtime or any other additional costs.
- 12.4 SATRA shall not be liable for the non-delivery of Goods (even if caused by SATRA) unless the Clik written notice of non-delivery in accordance with clause 13.2. Liability for non-delivery of Goods event be limited to replacing the Goods within a reasonable time frame or the issue of a credit of the control of th
- 12.6 If for any reason the Client fails to take delivery of any of the Goods whe SATRA is unable to deliver the Goods on time because the Client has rot; documents, lecreise or authoreations them in kin the Goods shall pass Services shall be deemed to have been delivered, and SATRA may store the the Client shall be table for all related costs and expenses (circlding,

- - 13.2.2 in all other cases the Client notifies SATRA on the non-arrival or damage in transit within a reasonable period of time as determined by SATRA.
- 13.3 Title to the Goods shall not pass to the Client until the earlier of when:
 - 13.3.1 SATRA receives payment in full (in cash or cleared funds) for the Goods and any other Goods that SATRA has supplied to the Client in which case title to the Goods shall pass at the time of payment of all such sums, and
 - 13.3.2 the Client reselts the Goods in accordance with clause 13.5 in which case title shall pass to the Client immediately before the time at which the resale by the Client occurs.

- - 13.4.1 hold the Goods as SATRA's bailee;
 - store the Goods (at no cost to SATRA) separately fr any third party in such a way that they remain readil where the Goods have been sold to a 3rd party);
 - not destroy, deface or obscure any identifying mark or packaging on or relating to the Go
- 13.5 The Client may resell the Goods before ownership has passed to it solely on effected in the ordinary course of the Client's business at full market value.
- 13.6 If before title to the Goods passes to the Client, the Client becomes subject to any of the events clause 2.6 then without limiting any other right or remedy SATRA may have:
 - 13.6.1 the Client's right to resell the Goods or use them in the ordinary course of its busi immediately; and
 - 13.6.2 SATRA may at any time require the Client to deliver up all Goods in its possession that heen resold or irrevocably incorporated into another product; and
 - 13.6.3 if the Client fails to do so promptly SATRA may exercise its rights under clause 13.7.
- 13.7 The Client grants SATRA, its agents and employees an irrevocable licence at any time to enter any tweet the Goods are or may be stored in order to inspect them, σr, where the Client's right to posses
- 13.8 On termination of a Contract, howsoever caused, SATRA's (but not the Client's) rights or clause 13 shall remain in effect.

16 DEFECTIVE GOODS

- - 16.1.1 the Client gives notice in writing to SATRA in accordance with clause 16.3 and during the per referred to in clause 15.1 that the Goods do not comply with the warranty in that clause; and
 - SATRA is given a reasonable opportunity of examining such Goods; and
 - 16.1.3 the Client (if asked to do so by SATRA) returns such Goods to SATRA's place of bus

- 16.2 The Client must inspect all Goods upon delivery. Failure to do so may result in further charges being applied in the event of a return.
- 16.3 If Goods are found to be faulty, defective or damaged the Client must inform SATRA in writing as soon as reasonably possible and in any event within 10 working days of the fault damage or defect being discovered. 16.4 Without prejudice to clause 16.1 if no notice of rejection has been received by SATRA within 3 months of delivery, the Client shall be deemed to have accepted the Goods.
- 16.5 SATRA will pay the reasonable costs of carriage, packaging and insurance for any defective Goods which are remained by the Client provided that SATRA is lable under clause 16.1 to repair or replace the defective Goods. If SATRA determines that the Goods are of defective or ISATRA in certal bat to prain or replace the Goods due to the circumstances under clauses 16.5 or 16.7 then the Client will be responsible for the payment of such costs.
- 16.6 SATRA shall not be under any liability to repair or at its option replace or pay for the repair or replace any Goods which are found to be defective if:

 - the Client has breached any of the terms of the Contract under which the Goods were
- 16.7 Where Goods or parts of Goods are not manufactured by SATRA then SATRA shall be liable for def to the extent that SATRA obtains redress from the manufacturer or supplier thereof provided that:

 - 16.7.2 nothing in this condition 16.7 shall have effect as to impose upon SATRA any additional configurations other than those referred to in condition 16.1.
- 16.8 Except as provided in clause 16.1 SATRA shall have no liability to the Client arising from any failure of the Goods to comply with the warranty in clause 15.1.

Signed:

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Adam Thang Zhang Technologist China Testing

SUNASAR AG +41 31 506 10 67 Bergblickweg 3 prz@sunamed.ch CH-6060 Sarnen www.sunamed.ch



Kontakt Bezug

Webseite:

www.sunamed.ch

SUNASAR AG Bergblickweg 3 CH-6060 Sarnen

Telefon +41 31 506 10 67 prz@sunamed.ch

Mais MI

Bestätigung

Dr. Klaus Huck, QM