

TECHNICAL REPORT

Shandong Intco Medical Products Co Ltd Qiwang Road, Naoshan Industrial Park Qingzhou SHANDONG 262506 China	SATRA reference:	CHT2021879	
		2513	1
	Report ID/Issue number:	50535/1	
	Your reference:		
	Date samples received:	24/03/2025	
	Date(s) work carried out:	03/04/2025 to 15/04/2025	
	Date of report:	17/04/2025	

Testing Requirements

EN ISO 374-2: 2019 clause 7.2 /7.3 – Air leak, Water leak, EN ISO 374-5: 2016 clause 5.3 – Viruses, EN ISO 21420: 2020 +A1: 2024 clause 5.1/5.2 – Size, Dexterity, Innocuousness (pH, PAHs) tests on Synthetic Latex Exam Gloves. Color: Cream White. Size: XS6, S7, M8, L9, XL10, XXL11.

For SATRA's full terms and conditions see our website: [Terms of business \[CN\] - SATRA](#)

For SATRA's statements regarding the confidentiality, publication and dissemination of this report, decision rules and UKAS accreditation please see the final page of this technical report.

Report Signed by:

Adam Zhang


Report Signatory

WORK REQUESTED

Samples described as Synthetic Latex Exam Gloves. Color: Cream White. Size: XS6, S7, M8, L9, XL10, XXL11 for testing in accordance with EN ISO 21420:2020+A1:2024, EN ISO 374-2:2019 and EN ISO 374-5:2016.

SAMPLE SUBMITTED



Synthetic Latex Exam Gloves

TESTING REQUESTED

- ≠EN ISO 21420:2020+A1:2024 Clause 5.1 – See below table
- ≠EN ISO 21420:2020+A1:2024 Clause 5.2 – Level 5
- EN ISO 374-2: 2019 Clause 7.2 – Air leak
- EN ISO 374-2: 2019 Clause 7.3 – Water leak
- ≠EN ISO 374-5: 2016 Clause 5.3 – Protection against viruses (ISO 16604: 2004 Procedure B)
- ≠EN ISO 21420:2020 Clause 4.2 – Innocuousness of protective gloves

CONCLUSION

The samples described as Synthetic Latex Exam Gloves. Color: Cream White. Size: XS6, S7, M8, L9, XL10, XXL11 were found to achieve the following results:

- ≠EN ISO 21420:2020+A1:2024 Clause 5.1 – See below table
- ≠EN ISO 21420:2020+A1:2024 Clause 5.2 – Level 5
- EN ISO 374-2: 2019 Clause 7.2 – Pass
- EN ISO 374-2: 2019 Clause 7.3 – Pass
- ≠EN ISO 374-5: 2016 Clause 5.3 – Pass
- ≠EN ISO 21420:2020+A1:2024 Clause 4.2 – Pass pH value and PAHs

Detailed results are included on the following page(s)

Table 4 – EN ISO 374-2:2019 Test Results

Clause / Test	Test Results	UoM (See note ♣)	Result
7.2 Air leak test	Total air pressure used	3.0 kPa	± 0.25 kPa
	Sample size	Leaks	
	XS6	No leaks detected	
	S7	No leaks detected	
	M8	No leaks detected	
	L9	No leaks detected	
	XL10 XXL11	No leaks detected	
7.3 Water leak test	Sample size	Leaks	N/A
	XS6	No leaks detected	
	S7	No leaks detected	
	M8	No leaks detected	
	L9	No leaks detected	
	XL10 XXL11	No leaks detected	

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.

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

Remark: '►' This test was started within five minutes after the specimens were removed from the defined conditions (23±2°C and 50±5% RH).

PROTECTION AGAINST VIRUSES TEST RESULTS

Testing was conducted at a third-party laboratory and reported under their reference 250067852. The laboratory is CNAS accredited to ISO 17025:2017 with ISO 16604:2004 included in their accreditation schedule.

Table 1 – Resistance to penetration by blood-borne pathogens results

Test Method: ISO 16604:2004 Procedure B

The support screen used: Retaining screen

The composition of the material: Synthetic Latex

Thickness of specimen(mm): 1# 0.08, 2# 0.08, 3# 0.08, average: 0.08

Mass per unit area of specimen(g/m²): 1# 80, 2# 80, 3# 80, average: 80

Results:

Sample description: Synthetic Latex Exam Gloves. Color: Cream White					
Pressure and time sequence	Specimen				
	Control (+)	Control (-)	1#	2#	3#
0kPa, 5min	Penetration	No visible penetration	No visible penetration	No visible penetration	No visible penetration
14kPa, 1min	Penetration	No visible penetration	No visible penetration	No visible penetration	No visible penetration
0kPa, 4min	Penetration	No visible penetration	No visible penetration	No visible penetration	No visible penetration
Assay titer (PFU/ml)	Penetration	< 1	< 1	< 1	< 1
Pass/Fail	Acceptable	Acceptable	Pass	Pass	Pass

INNOCUOUSNESS TESTING

Testing was conducted at a third-party laboratory and reported under their reference A112504070061. The laboratory is CNAS accredited to ISO 17025:2017.

TEST MATERIALS LIST OF CHEMICALS

Material(s) No.	Description	Location	Style	Remark
1	Beige soft plastic	Gloves	-	-

Note: The samples submitted by SATRA are described as CHT2021879 Synthetic Latex Exam Gloves. Color: Cream White.

TEST RESULTS

pH Value - EN ISO 21420:2020+A1: 2024

Test Method I : With reference to EN ISO 4045:2018, analyzed by pH meter.

Test Method II : With reference to ISO 3071:2020, Extract by KCL analyzed by pH meter.

Requirement:	3.5-9.5
---------------------	----------------

-	Unit	Result
Test Item(s)	-	1
Test Method	-	II
Parameter	-	-
Temp. of Aqueous Extract	°C	21.5
pH Value of Aqueous Extract	-	7.5
Difference Figure	-	-
Conclusion	-	PASS

Note / Key: deg. C = degree Celsius (°C) Temp. = Temperature

Remark: Result(s) was (were) reported the average value from two trials.

Polycyclic Aromatic Hydrocarbons (PAHs) Content - EN ISO 21420:2020+A1: 2024

Test Method : With reference to ISO 16190-2021 and analysis by Gas Chromatograph Mass Spectrometer.

Maximum Limit: Each of all listed PAHs: 1.0 mg/kg

Test Item(s)	Result		Unit	Conclusion
	Detected Analyte(s)	Conc.		
1	ND	ND	mg/kg	Pass

Note / Key: ND = Not detected (<Detection Limit) Detection Limit (mg/kg) : Each : 0.1;

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

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

Conditions of Use

Confidentiality and Dissemination

SATRA test reports may be forwarded to other parties provided that they are not changed in any way and are not marked as confidential. Test reports must not be published, for example by including it in advertisements, without the prior, written permission of SATRA.

Liability

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.

Accreditation

Where the UKAS logo is included on the test report then tests marked \neq fall outside the UKAS Accreditation Schedule for SATRA. Where no UKAS logo is included on the test report then none of the tests reported are covered by SATRA's UKAS Accreditation.

Uncertainty of Measurement and Decision Rules

Where values for uncertainty of measurement are included within the report then the uncertainty of the corresponding results are based on a standard uncertainty multiplied by a coverage factor $k=2$, which provides a coverage probability of approximately 95%.

When reporting results against a conformance statement (Pass/Fail or the allocation of a class or level) then uncertainty of measurement is taken into account based on a non-binary acceptance which itself is based on the guard band being equal to the expanded uncertainty.

Where the result corrected for uncertainty falls within the tolerance of the conformance statement then the risk of the conformance statement being a false accept or false reject is up to 2.5% and SATRA will in this instance quote a Pass/Fail, class, or level.

Where the result corrected for uncertainty falls outside of the tolerance of the conformance statement then the risk of the conformance statement being a false accept or false reject is up to 50%. In this instance SATRA will not provide a Pass/Fail statement or a class or level but will include information in the notes in relation to the result obtained.

Where a report contains SATRA guidelines values then uncertainty of measurement values have been taken into account when determining the guideline values and as such are not considered when determining pass/ fail criteria.
