




■ SGS Test Report—Nitrile Examination Gloves (FDA ASTM D6319)

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QDHL2011011723MD


Test Report

Report No.: QDHL2011011723MD

Sample Description:	DISPOSABLE GLOVES
Applicant:	5R MED INSTRUMENTS (CHENGDU) CO., LTD.
Test Type:	SUBMITTED BY CLIENT

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Test Report

	Sample Description	DISPOSABLE GLOVES	Color	BLUE
Sample information	Received sample quantity/ Tested sample quantity	S:200PCS, L:100PCS/ S:200PCS, L:35PCS	Type/Specifications	5R-GVN (S/L)
	Lot No.	20201026	Lot Quantity	35000
	Manufacture Date	2020-10-26	Expiration Date	2022-10-25
	Material/Appearance	BUTYRONITRILE	Storage Condition	HOME TEMPERATURE
	Manufacturer	5R MED INSTRUMENTS (CHENGDU) CO., LTD.		
	Client information	Applicant	5R MED INSTRUMENTS (CHENGDU) CO., LTD.	
Applicant address		BUILDING 9, SECTION 1, NO.618 OF WEST KELIN ROAD, CHENGDU CROSS-STRAITS TECHNOLOGY INDUSTRY DEVELOPMENT ZONE, WENJIANG DISTRICT, CHENGDU, SICHUAN PROVINCE, CHINA		

Please refer to check the authenticity of testing throughout the report & certificate, please contact us at tianhui@sgs.com (86-7345)00991855, or minnie.chi@cszhenyuan.com

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Test information	Sample Receiving Date	NOV.04,2020	Test Period Date	NOV.04,2020 TO NOV.27,2020
	Sample No.	QDHL2011011723MD	Test environment	Meet requirement
	Test items	Freedom from holes (For size S only), Physical dimensions (Length, Width, Thickness) (For size L only), Physical property characteristics (Tensile strength & Ultimate elongation before aging, Tensile strength & Ultimate elongation after aging)(For size L only), Powder residue for powder free gloves (For size L only), Packaging and package marking (For size L only)*		
	Testing Accordance	ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application Clause 6.1.2, 6.1.3, 6.1.4, 6.1.5, 9*		
Test conclusion	This report only provides the test results and individual judgment, conclusion please see follow pages. Issue date: NOV.27,2020			
Remark	/			

Approver: *Jessica Gu* Auditor: *Jessica Gu* Compiler: *Lillian Diao*
 Date: *2020.11.27* Date: *2020.11.27* Date: *2020.11.27*

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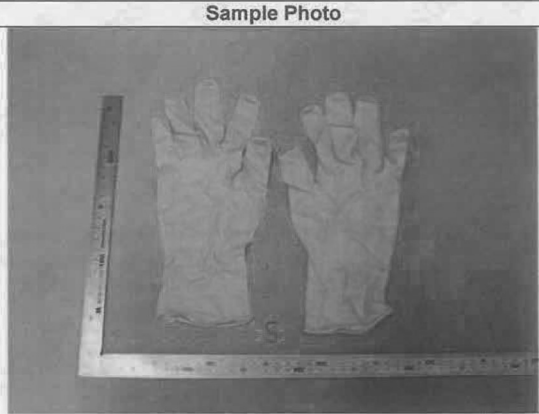
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Sample Photo



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Test Results

Test Items		Unit	Test Method	Requirement	Test Result	Assessment
Performance Requirements						
Freedom from Holes		/	ASTM D6319-19 Clause 6.1.2	Sample quantity: S: 200pcs AQL: 2.5 Ac: 10 Re: 11	Found: S: 0	Pass
Physical dimensions	Length	mm	ASTM D6319-19 Clause 6.1.3	L: ≥230	Sample quantity: L: 13pcs AQL: 4.0 Ac: 1 Re: 2	Pass
	Width	mm		L: 110±10		See appendix 1 for details
	Thickness-finger	mm		Median Value: ≥0.05		Pass
	Thickness-palm	mm		Median Value: ≥0.05		Pass
Physical property characteristics	Before Aging	Tensile strength	ASTM D6319-19 Clause 6.1.4	≥14	Sample quantity: L: 13pcs AQL: 4.0 Ac: 1 Re: 2	Pass
		Ultimate Elongation		≥500		See appendix 2 for details
	After Aging	Tensile strength		≥14		Pass
		Ultimate Elongation		≥400		Pass
Powder Residue For Powder Free Gloves		mg	ASTM D6319-19 Clause 6.1.5	≤2.0	L: 0.80	Pass

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Test Items	Unit	Test Method	Requirement	Test Result	Assessment
Packaging and Package Marking*					
Sterile Packaging	/	ASTM D6319-19 Clause 9.1	See appendix 3 for details	See appendix 3 for details	See appendix 3 for details
Nonsterile and Bulk Packaging	/	ASTM D6319-19 Clause 9.2			
Package Marking	/	ASTM D6319-19 Clause 9.3			

Appendix 1: Physical dimensions

Sample No.	Size: L			
	Length/mm	Width /mm	Median value /mm	
			Thickness-finger	Thickness-palm
1	256	112	0.125	0.096
2	253	113	0.125	0.095
3	254	113	0.137	0.095
4	255	112	0.125	0.094
5	256	113	0.126	0.096
6	257	113	0.124	0.094
7	253	113	0.122	0.094
8	254	113	0.121	0.093
9	258	113	0.124	0.094
10	258	113	0.126	0.098
11	254	113	0.122	0.096
12	256	113	0.122	0.093
13	259	113	0.132	0.097
Standard requirement	≥230	110±10	≥0.05	≥0.05
Found	0	0	0	0

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Appendix 2: Physical property characteristics

Size: L					
Before Aging			After Aging		
Sample No.	Tensile strength (Mpa)	Ultimate Elongation (%)	Sample No.	Tensile strength (Mpa)	Ultimate Elongation (%)
1	21.8	563	1	23.0	498
2	25.5	590	2	14.8	516
3	24.1	521	3	20.9	522
4	20.0	575	4	25.1	531
5	24.1	596	5	21.5	523
6	20.3	574	6	21.5	506
7	23.3	582	7	22.6	513
8	23.8	569	8	23.8	527
9	23.6	567	9	26.3	511
10	22.2	574	10	24.3	509
11	26.2	574	11	23.4	500
12	25.7	549	12	24.5	523
13	24.1	582	13	22.0	509
Standard requirement	≥14	≥500	Standard requirement	≥14	≥400
Found	0	0	Found	0	0

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Appendix 3: Packaging and Package Marking

Contents specified in the standard	Conformity	Regulatory requirements	Comments
1 Sterile Packaging	Not applicable	ASTM D6319-19 9.1	/
2 Nonsterile and Bulk Packaging			
2.1 The gloves shall be enclosed in an outer package that has sufficient strength to withstand normal transportation and storage within the cartons or shipping cases, or both.	Not conducted	ASTM D6319-19 9.2.1	No outer package was provided
2.2 None of the packaging material shall contain any material likely to impair the quality and use of the gloves.	Pass	ASTM D6319-19 9.2.2	No visible damage was found on gloves.
2.3 Cartons and shipping cases shall be of sufficient strength to maintain the quality of the product during normal transportation and storage.	Not conducted	ASTM D6319-19 9.2.3	No cartons and shipping cases were provided.
3 Package Marking			
3.1 Sterile packages shall bear markings for the contents to include the glove size, instructions for opening, the legend "sterile," and a manufacturing lot number.	Not applicable	ASTM D6319-19 9.3.1	Non-sterile
3.2 Nonsterile and bulk packages shall bear markings for the contents to include the glove size and a manufacturing lot number.	Pass	ASTM D6319-19 9.3.2	Glove size: L. Lot number: 20201026
3.3 The outermost case shall be labeled with the glove size and a manufacturing lot number. Sterile product cases shall also be marked with the legend "sterile."	Not conducted	ASTM D6319-19 9.3.3	No outermost case was provided.
3.4 All levels of packaging shall conform to all appropriate government labeling regulations.	Pass	ASTM D6319-19 9.3.4	/

Remarks:

- * Test items were not included in the CNAS accredited schedule for our laboratory.
- The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.
- Packaging and Package Marking assessment was based on the information provided by the customer, excluding the verification of the authenticity of the content. SGS is not responsible for verifying the accuracy of the information provided by customers.

End of Report

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