

No.: XMHL2010010076CW

Date: Oct 28, 2020

Page 1 of 4

FUJIAN JIXIANG MEDICAL TECHNOLOGY CO., LTD 29 TINGZHOU AVENUE SOUTH ROAD, CEWU TOWN, CHANGTING COUNTY, FUJIAN PROVINCE

Sample Description

: DISPOSABLE PVC GLOVES

As above test item and its relevant information regarding to the submission are provided and confirmed by the applicant. SGS is not liable to either the test item or its relevant information, in terms of the accuracy, suitability, reliability or/and integrity accordingly.

SGS Ref No.	: QDHL2010010644MD
Sample Receiving Date	: Oct 10, 2020
Test Performing Date	: Oct 10, 2020 to Oct 28, 2020
Test Performed	: Selected test(s) as requested by applicant
Test Result(s)	: For further details, please refer to the following page(s)

Signed for and on behalf of SGS-CSTC Standards Technical Services Co., Ltd. Xiamen Branch

Beck



Beck Hong Authorized Signatory



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at http://www.sgs.com/en/Terms-and-Conditions.aspx and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at http://www.sgs.com/en/Terms-and-Conditions/Terms-en-Document.aspx. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document cannot be reproduced except in full, without prior writen approval of the Company. Any unauthorized alteration, forgery or faisification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results hown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only. Attention:To check the authenticity of testing / inspection report & certificate, please contact us at telephone:(86-755) 8307 1443, or email: CN-Doccheck@sgs.com

No.31 Xianghong Road, Xiang'An Torch Industrial Zone, Xiamen, Fujian Province, China 361101 t (86–592) 5766537 f (86–592) 5766460 www.sgsgroup.com.cn 中国 ·福建 ·厦门 · 火炬(翔安)产业区翔虹路31号 邮编: 361101 t (86–592) 5766537 f (86–592) 5766460 e sgs.china@sgs.com



No.: XMHL2010010076CW

Date: Oct 28, 2020

Test items	Water tightness test, Tensile strength (Force at break, Force at break after challenge				
Test items	testing), Removable surface powder, Proteins, leachable				
Testing Accordance	EN 455-1:2020 Medical Gloves for Single Use – Part 1: Requirements and Testing				
	for Freedom from Holes Clause 5.1				
	EN 455-2:2015 Medical Gloves for Single Use – Part 2: Requirements and Testing				
	for Physical Properties Clause 5.2,5.3				
	EN 455-3:2015 Medical Gloves for Single Use – Part 3: Requirements and Testing				
	for Biological Evaluation Clause 4.4,4.5				

Test Results

Test	Items	Unit	Test Method	Requirement	Test Result	Assessment
Water tightness test		/	EN455-1: 2020 Clause 5.1	Sample quantity: 200pcs AQL: 1.5 Ac: 7 Re: 8	Found: 0	Pass
Tensile strength	Force at break	N	EN 455-2: 2015 Clause 5.2	Median value: ≥3.6	See appendix 1 for details	Pass
	Force at break after challenge testing	N	EN 455-2: 2015 Clause 5.3	Median value: ≥3.6		Pass
Removable surface powder		mg	EN 455-3: 2015 Clause 4.4 EN ISO 21171:2006	≤2	0.10	Pass
Proteins, leachable		µg/g	EN 455-3: 2015 Clause 4.5	/	Not detected (Method Detection Limit: 10)	/



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at http://www.sgs.com/en/Terms-and-Conditions.aspx and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at http://www.sgs.com/en/Terms-and-Conditions.terms-e-Document.aspx. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only. Attention: To check the authenticity of testing / inspection report & certificate, please contact us at telephone:(86-755) 8307 1443, or email: CN-Doccheck@sgs.com

 1443, or email: CN.Doccheck@sgs.com

 No.31 Xianghong Road, Xiang'An Torch Industrial Zone, Xiamen, Fujian Province, China 361101 t (86–592) 5766537 f (86–592) 5766460 www.sgsgroup.com.cn

 中国・福建・厦门・火炬(翔安) 产业区翔虹路31号
 邮编: 361101 t (86–592) 5766537 f (86–592) 5766660 e sgs.china@sgs.com



No.: XMHL2010010076CW

Page 3 of 4

Appendix 1: Tensile strength

Size: M						
Force at break (N)						
Befo	ore aging	After aging				
No.	/	No.	/			
1	4.3	1	3.6			
2	3.6	2	3.8			
3	4.0	3	3.7			
4	4.0	4	4.1			
5	4.0	5	3.8			
6	4.2	6	3.8			
7	4.8	7	4.3			
8	4.4	8	3.7			
9	4.0	9	4.5			
10	3.9	10	3.6			
11	4.0	11	3.5			
12	4.1	12	4.2			
13	4.3	13	4.0			
Standard requirement	≥3.6	Standard requirement	≥3.6			
Median value	4.0	Median value	3.8			

Remark:

- 1. The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.
- 2. This test was subcontracted to Qingdao Branch, SGS-CSTC Co., Ltd.



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at http://www.sgs.com/en/Terms-and-Conditions.aspx and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Document.aspx. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document for unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only. Attention: To check the authenticity of testing / inspection report & certificate, please contact us at telephone:(86-755) 8307 1443, or email: CN.Doccheck@gs.com

No.31 Xianghong Road, Xiang'An Torch Industrial Zone, Xiamen, Fujian Province, China 361101 t (86–592) 5766537 f (86–592) 5766460 www.sgsgroup.com.cn 中国・福建・厦门・火炬(翔安)产业区翔虹路31号 邮编: 361101 t (86–592) 5766537 f (86–592) 5766460 e sgs.china@sgs.com



No.: XMHL2010010076CW

Date: Oct 28, 2020

Page 4 of 4



End of Report



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at http://www.sgs.com/en/Terms-and-Conditions.aspx and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Document.aspx. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only. Attention: Cocheck the authenticity of testing / inspection report & certificate, please contact us at telephone:(86-755) 8307 1443, or email: CN.Doccheck@sgs.com

No.31 Xianghong Road, XiangAn Torch Industrial Zone, Xiamen, Fujian Province, China 361101 t (86-592) 5766537 f (86-592) 57666460 www.sgsgroup.com.cn 中国・福建・厦门・火炬(翔安)产业区翔虹路31号 邮编: 361101 t (86-592) 5766537 f (86-592) 5766460 e sgs.china@sgs.com