



中国认可
国际互认
检测
TESTING
CNAS L0604

To check the authenticity of testing/inspection reports/certificate, please contact us at telephone: (86-755) 8169 4445, or email: CH.Doc@sgs.com

Test Report

No.: QDHL2005004254MD-01_EN Date: JUN.12.2020 Page: 1 of 8

THIS REPORT IS TO SUPERSEDE TEST REPORT NO.: QDHL2005004254MD, DATE: JUN.11.2020. THE ORIGINAL REPORT SHALL BECOME INVALID AS OF THE DATE OF ISSUANCE OF THIS REPORT.

Client name : JIANGXI KEMEI MEDICAL APPARATUS & INSTRUMENTS GROUP CO., LTD.
 Client address : NO.316 NATIONAL ROAD, XINJU, CHANGSHAN TOWN, JINXIANG COUNTY, NANCHANG CITY, JIANGXI PROVINCE, CHINA
 Sample Description : EXAMINATION GLOVES -TYPE A (LATEX GLOVES)
 Lot No. : 20200510
 Lot Size : 10000PAIRS
 Sample Quantity : 700PCS
 Manufacturer : JIANGXI KEMEI MEDICAL APPARATUS & INSTRUMENTS GROUP CO., LTD.
 Manufacturer Date : MAY.10,2020
 Appearance : POWDER FREE TEXTURED
 Storage Condition : ROOM TEMPERATURE

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.

Sample Receiving Date : MAY.15,2020
 Test Performing Date : MAY.15,2020 TO JUN.11,2020



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-Documents.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 is unlawful and offenders may be prosecuted to the fullest extent of the law.

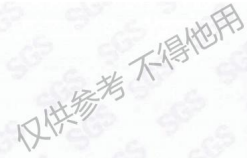
SGS Center, No. 143, Zhuzhou Road, Laoshan District, Qingdao, China 286101
 t (86-532) 68999888 f (86-532) 80991855

7385199
 www.sgs.com.cn
 sgs.china@sgs.com

Member of the SGS Group (SGS SA)



中国认可
国际互认
检测
TESTING
CNAS L0604



To check the authenticity of testing (inspection) report & certificate, please contact us at telephone: (86-755) 26170443, or email: CN.Docs@sgs.com

Test Report

No.: QDHL2005004254MD-01_EN

Date: JUN.12.2020

Page: 2 of 8

Test Requested	Result
1. BS EN 455-1:2000 Medical Gloves for Single Use – Part 1: Requirements and Testing for Freedom from Holes (Clause 5.1)	Pass
2. BS EN 455-2:2015 Medical Gloves for Single Use – Part 2: Requirements and Testing for Physical Properties (Clause 4.2, 4.3, 5.2, 5.3, 7*)	Pass
3. BS EN 455-3:2015 Medical Gloves for Single Use – Part 3: Requirements and Testing for Biological Evaluation (Clause 4.2*, 4.4, 4.5*, 4.6*)	See Results

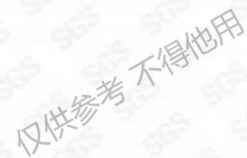
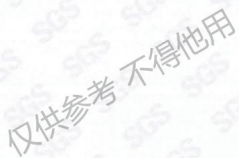
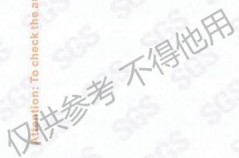
Remark: - Unless otherwise stated the results shown in this test report refer only to the sample(s) tested. This document cannot be used for publicity, without prior written approval of the SGS.

SGS-CSTC Standards
Technical Services (Qingdao)
Co., Ltd.

Jessica Gao



Jessica Gao
Approved 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-e-Documents.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 is unlawful and offenders may be prosecuted to the fullest extent of the law.

SGS Center, No. 143, Zhuzhou Road, Laoshan District, Qingdao, China 266101
t (86-532) 68998888 f (86-532) 80861855

QD 7395490
www.sgs.com.cn
sgs.china@sgs.com

Member of the SGS Group (SGS SA)



中国认可
国际互认
检测
TESTING
CNAS L0604

Test Report

No.: QDHL2005004254MD-01_EN

Date: JUN.12.2020

Page: 3 of 8

Test Conducted:

1. BS EN 455-1:2000 Medical gloves for single use – Part 1: Requirements and testing for freedom from holes

Number of test sample	: 200 Pieces
Sample size	: M
Number of non-conforming gloves	: 6PCS

Clause	Test Items	Result
5	Watertightness test for detection of holes	---
5.1	Referee testing	Pass (See note 1)

Note : 1 Sample quantity: 200pcs, AQL:1.5, Ac:7, Re:8, Found:6.
The sample selecting amount for this clause is deviated to 200 pcs as assessed by SGS.

2. BS EN 455-2:2015 Medical gloves for single use – Part 2: Requirements and testing for physical properties

Number of test sample	: 26 Pieces
Type	: Examination/procedure gloves: b)
Size	: Examination/procedure gloves: M

Clause	Test Items	Result
4	Dimensions	---
4.2	Length	Pass (See result 1)
4.3	Width	Pass (See result 1)
5	Strength	---
5.2	Force at break	Pass (See result 2)
5.3	Force at break after challenge testing	Pass (See result 2)
7*	Labelling	Pass (See note 1)

Note : 1 Date of manufacture: 2020-05-10

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-Documents.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 is unlawful and offenders may be prosecuted to the fullest extent of the law.



SGS (Shanghai) Inspection & Testing Services Co., Ltd.
Technical Services (China) Co., Ltd.
Technical Services

SGS Center, No. 143, Zhuzhou Road, Laoshan District, Qingdao, China 266101
t (86-532) 68998888 f (86-532) 80801655

QD

7395491

www.sgs.com
sgs.china@sgs.com

Member of the SGS Group (SGS SA)



中国认可
国际互认
检测
TESTING
CNAS L0604

To check the authenticity of testing/inspection report/certificate, please contact us at telephone: (86-755) 26171443, or email: CN.Dashboard@sgs.com

Test Report

No.: QDHL2005004254MD-01_EN

Date: JUN.12.2020

Page: 4 of 8

Result 1: Dimensions

Size No.	Length (mm)	M	Width (mm)
1	249		95
2	245		96
3	250		97
4	246		95
5	247		95
6	250		97
7	249		96
8	248		96
9	247		96
10	248		96
11	248		95
12	246		96
13	250		96
Standard requirement	≥240		95±10
Median value	248		96

Result 2: Strength

No.	Size: M			
	Force at break (N)			
	Before aging		After aging	
	/	No.	/	
1	9.7	1	8.9	
2	9.2	2	9.1	
3	10.5	3	9.1	
4	10.1	4	10.0	
5	9.8	5	9.2	
6	9.4	6	8.6	
7	10.7	7	10.0	
8	10.7	8	10.0	
9	10.5	9	10.4	
10	10.0	10	9.6	
11	10.3	11	9.0	
12	10.3	12	9.2	
13	9.7	13	9.2	
Standard requirement	≥6.0	Standard requirement	≥6.0	
Median value	10.1	Median value	9.2	



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-Documents.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 is unlawful and offenders may be prosecuted to the fullest extent of the law.

SGS CS (China) Technical Services (Qingdao) Co., Ltd.

SGS Center, No. 143, Zhuzhou Road, Laoshan District, Qingdao, China 266101
t (86-532) 6899888 f (86-532) 80981865

QD

7385192

www.sgs.com.cn
sgs.china@sgs.com

Member of the SGS Group (SGS SA)



中國認可
國際互認
檢測
TESTING
CNAS L0604

Test Report

No.: QDHL2005004254MD-01_EN

Date: JUN.12.2020

Page: 5 of 8

3. BS EN 455-3:2015 Medical gloves for single use – Part 3: Requirements and testing for biological evaluation

Number of test sample	: 5 Pieces
Finishes of gloves	: Powdered-free gloves other than surgeon's gloves
Size	: M

Clause	Test Items	Result
4.2*	Chemicals	See Result 1
4.4	Powder-free gloves	Pass (See note 1)
4.5*	Proteins, leachable	See Result 2
4.6*	Labelling	Pass

Note : 1 Test according to EN ISO 21171:2006, the average mass of powder per glove is 0.02mg. (Requirement: ≤2mg per powder-free glove)

Result 1: Chemicals

Name	Cas No.	Concentration	Classification & Labelling
Information on ingredients of product:			
1,3-Butadiene, 2-methyl-, homopolymer	9003-31-0	92%	
Sulphur	63705-05-5	1%	No results found
accelerator EZ	136-94-7	1%	No results found
zinc oxide	1314-13-2	1%	⚠ Aquatic Acute 1, H400; Aquatic Chronic 1, H410
2,6-di-tert-butyl-p-cresol	128-37-0	1%	
Titanium oxide	1317-80-2	0.15%	
Calcium carbonate	471-34-1	3%	
Caseins	9000-71-9	0.425%	
potassium hydroxide	1310-58-3	0.425%	⚠ Skin Corr. 1A, H314; Acute Tox. 4, H302
Information on other substances used manufacturing process:			
Not provided			

The classification is according to the latest edition of Regulation (EC) No 1272/2008, and extended by company and literature data

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-Documents.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 is unlawful and offenders may be prosecuted to the fullest extent of the law.



SGS Center, No. 143, Zhuzhou Road, Laoshan District, Qingdao, China 266101
t (86-532) 68998888 f (86-532) 80881655

QD

7395193

www.sgs.com.cn
sgs.china@sgs.com

Member of the SGS Group (SGS SA)



中国认可
国际互认
检测
TESTING
CNAS L0604

To check the authenticity of testing / inspection reports & certificates, please contact us at telephone: (86-755) 26651449, or email: CN.Docs@sgs.com

Test Report

No.: QDHL2005004254MD-01_EN

Date: JUN.12.2020

Page: 6 of 8

Result 2: Proteins, leachable

Test Item	Result
Aqueous extractable protein	52.4

Remark:

- 1: $\mu\text{g/g}$ = microgram per gram.
- 2: Detection limit of aqueous extractable protein is 10 $\mu\text{g/g}$.

Remark:

1. * Test items were not included in the CNAS accredited schedule for our laboratory.
2. The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.
3. Labelling test review 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.
4. The marked * part is the modification information.

Sample Photo^:

Received Sample



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-Documents.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 is unlawful and offenders may be prosecuted to the fullest extent of the law.

SGS Center, No. 143, Zhuzhou Road, Laoshan District, Qingdao, China 266101
t (86-532) 68998888 f (86-532) 80861655

QD

7325434

www.sgs.com.cn
sgs.china@sgs.com

Member of the SGS Group (SGS SA)

To check the authenticity of testing / inspection reports & certificate, please contact us at telephone: (86-755) 8149 1449, or email: CN.Detect@sgs.com

Test Report

No.: QDHL2005004254MD-01_EN

Date: JUN.12.2020

Page: 7 of 8

Packaging (Artwork)- overall view▲



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-Documents.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 is unlawful and offenders may be prosecuted to the fullest extent of the law.

SGS Center, No. 143, Zhuzhou Road, Laoshan District, Qingdao, China 266101
t (86-532) 68999888 f (86-532) 80801855

7385195
www.sgs.com.cn
sgs.china@sgs.com

仅供参考 不得他用
SGS



中国认可
国际互认
检测
TESTING
CNAS L0604

仅供参考 不得他用

For information: To check the authenticity of testing/inspection reports & certificates, please contact us at telephone: (86-755) 26171443, or email: CN.Decreback@sgs.com

Test Report

No.: QDHL2005004254MD-01_EN

Date: JUN.12.2020

Page: 8 of 8

Packaging (Artwork)- detail view^

Storage: the product should be stored in a cool, dry, well-ventilated and clean room with relative humidity not exceeding 80% and no corrosive gases.

Jiangxi Kemei Medical Apparatus & Instruments Group Co., Ltd.
No. 316, National Road, Xinju Village, Changshan Town, Jinxian District,
Nanchang City 331724 Jiangxi, China

MedPath GmbH Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

SGS authenticate the photo on original report only

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-Documents.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 is unlawful and offenders may be prosecuted to the fullest extent of the law.

SGS Center, No. 143, Zhuzhou Road, Laoshan District, Qingdao, China 266101
t (86-532) 6899888 f (86-532) 80981865

QD 7385196

www.sgs.com.cn
sgs.china@sgs.com

Member of the SGS Group (SGS SA)