中国认可 国际互认 检测 TESTING CNAS L0604

No.: QDHL2005004254MD-01_EN

Date: JUN.12.2020 Page: 1 of 8

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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

Sample Description

Client address

Lot No.

Lot Size Sample Quantity

Manufacturer

Appearance 120,

Test Report

JIANGXI KEMEI MEDICAL APPARATUS & INSTRUMENTS GROUP CO., LTD. NO.316 NATIONAL ROAD, XINJU, CHANGSHAN TOWN, JINXIAN COUNTY, NANCHANG CITY, JIANGXI PROVINCE, CHINA EXAMINATION GLOVES - TYPE A (LATEX GLOVES) 20200510 10000PAIRS

700PCS

JIANGXI KEMEI MEDICAL APPARATUS & INSTRUMENTS GROUP CO., LTD.

MAY.10,2020

Manufacturer Date Storage Condition

POWDER FREE TEXTURED : 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 Test Performing Date

MAY.15,2020 MAY.15,2020 TO JUN.11,2020

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Member of the SGS Group (SGS SA)







Test Requested

Test Report

- 1. BS EN 455-1 2000 Medical Gloves for Single Use Part 1: Requirements and Testing for Freedom from Holes (Clause 5.1)
- 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*)
- Result Pass Pass With the Konstant See Results

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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*)

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.



* S Ć	S	CNAS	大化計批用 中国认可 国际互认 检测 TESTING CNAS L0604	风快等考不知	Htt
Test	Report No.: QDH	IL2005004254MD-01	LEN Date: JUN.12.2020	Page: 3 of 8	
Test Condu	cted:				
	N 455-1:2000 Medical glo om from holes	oves for single use	- Part 1: Requirements and tes	sting for	副他
Number	of test sample	: 200 Pieces	1 5 2 L 5	in the A	
Sample s		: M H	6 6° 7	1 the second	
	of non-conforming gloves	: 6PCS	7 5 8 9	1XV	
	: 1 The sample s by SGS.	selecting amount for t	Pass (See note 1) 5, Ac:7, Re:8, Found:6. his clause is deviated to 200 pcs – Part 2: Requirements and tes		副性
- XA	of test sample	: 26 Pieces	<u>N · · · · · · · · · · · · · · · · · · ·</u>	izta 1	
Type		10/11	cedure gloves: b)	N HE	
Size	25 do 9		cedure gloves: M	NY-	
Clause 4	<u>Test Items</u> Dimensions Length Width Strencth	50 55 5 56 55 55 55	Result Pass (See result 1) Pass (See result 1) Pass (See result 2)	50 555 555 55 50 555 555 55 555 555 55	
4.2 4.3 5 5.2 5.3 7* Note,	Force at break Force at break after cha Labelling	Illenge testing Inufacture: 2020-05- WHAT	Pass (See result 2) Pass (See note 1)	风快等考不帮	副性

ocument is issued by the Company subject to its General Conditions of Service printed at http://www.sgs.com/en/Terms-and-Conditions.aspx and, for electronic format documents, onic Documents at http://www.sgs.com/en/Terms-and-Conditions/Terms-Document.aspx. ity, indemnification and jurisdiction issues defined therein. Any holder of this document is reflects the Company's findings at the time of its intervention only and within the limits of and obligations, under the transaction documents. This document cash to be reproduced, al of the Company, individual alteration, forgery or faisfication on the content or of officient of the processication to the lew. Unless of overleaf, a subject to Attention advised th Client's in transactio except in appearance \$< (青岛 r Electro of liabili action fr Allow, houghly of allowing and of the content of at extent of the law. SGS Center, No. 143, Zhuzhou Road, Laochan Dietrick Clingdao, China 266101 t (86–532) 68999888 f (86–532) 80991855

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Ie	st Report	No.: QDHL200500425	4MD-01_EN Date: J	UN.12.2020 Page: 4 of	8
Result 1	: Dimensions				
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	12	195 - 195 - 195 - 195 - 195 - 195 - 195 - 195 - 195 - 195 - 195 - 195 - 195 - 195 - 195 - 195 - 195 - 195 - 195	250	96	1200
5	Standard require	ment	≥240	95±10	-
-	Median value		248	96	0.0
. C? -	NEG VIII		HER.		-
Result 2	: Strength		I.E. (BIT.	40 - 7 - 5 - 6	一一月代
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0.01	2 3	<u>9.2</u> 10.5	3	9.1	100
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	5	9.8	5	9.2	650
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5	7	10.7	7	10.0	8 8
2.50	8	10.7	8	10.0	3
-	9	10.5	9	10.4	50
2.9	10	10.0	10	9.6	-62
S	1,40,FD	10.3	1140,89	9.0	- 12
92	11312	10.3	112	9.2	
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JANS .	Standard requirement	≥6.0	Standard requirement	≥6.0	考不得性
		10.1	Median value	9.2	

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| 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 Number of test sample : 5 Pieces Powdered-free gloves other than surgeon's gloves Finishes of gloves Size : Powdered-free gloves other than surgeon's gloves Size Clause Test Items Result See Result 1 4.2* Chemicals See Result 2 Pass (See note 1) 4.5* Proteins, leachable See Result 2 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) esult 1: Chemicals | 3. 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21171:2006, the average mass of powder per glove is 0.02mg. (Requirement: ≤2mg per powder-free glove) It 1: Chemicals Varie 1 Cas No. Marie Cas No. Concentration Information on ingredients of product: 1 Nomopolymer 9003-31-0 92% Sulphur 63705-05-5 1% No results found 1 | 4.4 Powder-free gloves Pass (See note 1) .5* Proteins, leachable See Result 2 .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) 1: Chemicals arrection Cas No. formation on ingredients of product: 3-Butadiene, 2-methyl-, 900-31-0 92% ulphur 63705-05-5 1% No results found No results found | 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) t 1: Chemicals Cas No. Concentration Image: Cas No. Concentration Classification & Labelling nformation on ingredients of product: | 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) It 1: Chemicals | |
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| 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) esult 1: Chemicals Name Cas No. Concentration Classification & Labelling Information on ingredients of product: 1,3-Butadiene, 2-methyl-, 9003-31-0 92% Pass Sulphur 63705-05-5 1% No results found Information on ingredient per glove is 0.02mg. Sulphur 63705-05-5 1% No results found Information per glove is 0.02mg. | 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) sult 1: Chemicals Name Cas No. Concentration Classification & Labelling Information on ingredients of product: 1,3-Butadiene, 2-methyl-, 9003-31.0 92% 1 Information on ingredients of product: 1,3-Butadiene, 2-methyl-, 10003-31.0 92% 1 Sulphur 63705-05-5 1% No results found 1 accelerator EZ 136-94-7 1% No results found zinc oxide 1314-13-2 1% Aquatic Acute 1, H400; | 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) sult 1: Chemicals Cas No. Concentration Classification & Labelling Information on ingredients of product: 1 92% 1 1,3-Butadiene, 2-methyl-, homopolymer 9003-31.0 92% 1 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 | 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) sult 1: Chemicals Cas No. Concentration Classification & Labelling Information on ingredients of product: 1 92% 1 1,3-Butadiene, 2-methyl-, homopolymer 9003-31.0 92% 1 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 | 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) sult 1: Chemicals Cas No. Concentration Classification & Labelling Information on ingredients of product: 1,3-Butadiene, 2-methyl-, 9003-31-0 92% 1 1,3-Butadiene, 2-methyl-, 9003-31-0 92% 1 1 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; | 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) sult 1: Chemicals Cas No. Concentration Classification & Labelling Information on ingredients of product: 1,3-Butadiene, 2-methyl-, 9003-31-0 92% 1 Information or ingredients of product: 1,3-Butadiene, 2-methyl-, 9003-31-0 92% 1 Sulphur 63705-05-5 1% No results found 1 accelerator EZ 136-94-7 1% No results found zinc oxide 1314-13-2 1% Aquatic Acute 1, H400; | 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) sult 1: Chemicals Cas No. Concentration Classification & Labelling Information on ingredients of product: 1,3-Butadiene, 2-methyl-, 9003-31-0 92% 1 Information or ingredients of product: 1,3-Butadiene, 2-methyl-, 9003-31-0 92% 1 Sulphur 63705-05-5 1% No results found 1 accelerator EZ 136-94-7 1% No results found zinc oxide 1314-13-2 1% Aquatic Acute 1, H400;
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Test Report No.: QDHL2005004254MD-01_EN Date: JUN.12.2020 Page: 6 of 8

Result 2: Proteins, leachable

Test Item	Result	2
Aqueous extractable protein	天代 52.4	老天得到
mark:	风梯	STIN S

中国认可 国际互认 检测 TESTING **CNAS L0604**

Remark:

1: µg/g = microgram per gram.

2: Detection limit of aqueous extractable protein is 10 µg/g.

Remark:

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

Sample Photo 4:

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