Test Report No. 7191232801-EEC20-WBH dated 13 Mar 2020

Note: This report is issued subject to the Testing and Certification Regulations of the TÜV SÜD Group and the General Terms and Conditions of Business of TÜV SÜD PSB Pte Ltd. In addition, this report is governed by the terms set out within this report.

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SUBJECT:

Testing of Gloves submitted by Jiangsu Cureguard Glove Co., Ltd on 28 Feb 2020 and 11 Mar 2020

TESTED FOR:

江苏尤佳手套有限公司/Jiangsu Cureguard Glove Co.,Ltd 江苏省宿迁市经济开发区深圳路65号 No.65, Shenzhen Road, The Economic Development Zone Of Suqian City, Jiangsu, 223800 China

TEST DATE:

28 Feb 2020 to 12 Mar 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Brand	Size	Lot No.	Sample received (pieces)	Manufacturer
1	一次性 PVC 手套 Disposable PVC Gloves		M	20200219	400	Jiangsu cureguard glove Co. Ltd.

Lot size as specified by client: 150,001 to 500,000 pieces

METHOD OF TEST:

The tests were conducted in accordance with the following standards as requested by client:

- 1. EN 455-1:2000 Medical gloves for single use Part 1: Requirements and testing for freedom from holes
- EN 455-2:2015 Medical gloves for single use Part 2: Requirements and testing for physical properties
 - -Clause 4 Dimensions
 - -Clause 5 Strength



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RESULTS:

Sample: 一次性 PVC 手套 Disposable PVC Gloves, Lot No. 20200219, Size M

Table 1: Results for EN 455-1:2000

Clause	Tests	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
4 5	Freedom from holes	Shall not leak	10	315	0	Passed

Table 2: Results for EN 455-2:2015 Clauses 4-5

Clause	Tests	Requirements (Median)	Number tested (pieces)	Results (Median)	Inferred results
4	Dimensions a) Length (mm)	≥ 240	13	245	Passed
4	b) Width (mm)	For Size M: 95 ± 10	13	97	Passed
-	Strength a) Force at break (N)	For vinyl examination gloves: ≥ 3.6	13	4.2	Passed
5	b) Force at break after challenge testing (N) 7 days at (70±2)°C	For vinyl examination gloves: ≥ 3.6	13	4.3	Passed

Yeo Poh Kwang Associate Engineer

Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:



Photo: 一次性 PVC 手套 Disposable PVC Gloves, Lot No. 20200219, Size M

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Please note that this Report is issued under the following terms:

- 1. This report applies to the sample of the specific product/equipment given at the time of its testing/calibration. The results are not used to indicate or imply that they are applicable to other similar items. In addition, such results must not be used to indicate or imply that TÜV SÜD PSB approves, recommends or endorses the manufacturer, supplier or user of such product/equipment, or that TÜV SÜD PSB in any way "guarantees" the later performance of the product/equipment. Unless otherwise stated in this report, no tests were conducted to determine long term effects of using the specific product/equipment.
- 2. The sample/s mentioned in this report is/are submitted/supplied/manufactured by the Client. TÜV SÜD PSB therefore assumes no responsibility for the accuracy of information on the brand name, model number, origin of manufacture, consignment or any information supplied.
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- 5. Unless otherwise stated, the tests were carried out in TÜV SÜD PSB Pte Ltd, No.1 Science Park Drive Singapore 118221.



July 2011





Jiangsu Cureguard Glove Co. Ltd No. 65 Shenzhen Road The Economic Development Zone Suqian Jiangsu 223800 China

Notified Body: 2777

SATRA customer number: P19031

EU Type-Examination Certificate

Certificate number: 2777/12581-02/E00-00

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation:

Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

Product reference: Description:

CG-01 Disposable PVC Powdered and powder-free gloves

Powder Free – available in clear, blue, black, pink, white and yellow.

Powdered – available in clear and blue.

Sizes: Classification:

5/XS, 6/S, 7/M, 8/L, 9/XL

EN ISO 374-1:2016+A1:2018 / Type B

30% Hydrogen peroxide (P)

40% Sodium Hydroxide (K)

n-Heptane (J)

37% Formaldehyde (T)

Level

5 0.7 %

5 -1.3 %

2.0 %

-11.3 %

EN ISO 374-5: 2016

Protection against Bacteria and fungi Pass Protection against viruses Pass

Standards/Technical specifications applied:

EN 420: 2003+A1: 2009; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

Technical reports/Approval documents:

SATRA: CHT0279759/1902/JG/B, CHT0279759/1902/JG/A, CHT0278782/1849/LH/A, CHT0278782/1849/LH/B,

CHT0278782/1849/SPT Issue 2, CHT0278782/1849, CHT0290175/1939, CHM0291665/1945/LH

Nelson Labs: 1057952-S01.1, 1057952-S01, 1055741-S01

Signed on behalf of SATRA:

Date first issued: 15/04/2019 Date of issue: 23/01/2020 Ting Huand Ting Huang

abl

Quincey Brown

Expiry date: 15/04/2024

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TERMS AND CONDITIONS

The following conditions apply in addition to SATRA's standard terms and conditions of business and those given in the current certification agreement.

The certificate holder is licensed to mark the products detailed within this certificate in accordance with Annex V (Module B) of the Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment once you have drawn up an EU declaration of product conformity.

Please note:

- 1. Where the product is classified as category III then CE Marking of production is reliant on current compliance with Regulation 2016/425 module C2 or Module D. (Except that specifically produced to fit an individual user).
- 2. Full details of the scope of the certification and product(s) certified are contained within the manufacturer's technical documentation.
- 3. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
- 4. Certification is limited to production undertaken at the sites listed in the manufacturers technical documentation.
- 5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate.
- 6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
- 7. Where results obtained during type testing are within the budget of uncertainty when compared to the pass requirement, classification or performance level, then it is the responsibility of the manufacturer to ensure that the factory production control and manufacturing tolerances are such that the product placed on the market meets with the stated requirements, classifications or performance levels.
- 8. This certificate shall be kept together with the relevant technical documentation in a safe place by the client named on this certificate. Production of this certificate and other documentation may be required by a representative of the EC member state government.
- 9. This certificate relates only to the condition of the testable items at the time of the certification procedure and is subject to the expiry date shown.
- SATRA reserves the right to withdraw this certificate if it is found that a condition of manufacture, design, materials or packaging have been changed and therefore no longer comply with the requirements of Regulation 2016/425.