
DISPOSABLE VINYL GLOVES
Small
Medium
Large
X-Large
Quantity
1000 pcs
LOT NO: LB200520


DISPOSABLE VINYL GLOVES
Quantity
1000 pcs
Small
Medium
Large
X-Large
POWDERED
POWDER FREE
SYNTHETIC
CLEAR
BLUE
NON STERILE
MADE IN CHINA
VINYL GLOVES
BLUE
SYNTHETIC
POWDER FREE
NON STERILE
MADE IN CHINA
SH0030BT1

Vinyl

DISPOSABLE GLOVES

Protection légère tout-usage pour les mains

Features:

- Anti-bacterial formulation
- Durable and tear resistant
- Liquid proof

100 gloves

SATRA TECHNOLOGY

Issued to:

[redacted]

China

Notified Body: 2777

SATRA customer number: P1724

EU Type-Examination Certificate

Certificate number: 2777/11628-01/E01-01

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:

All Fine GL-TF-PVC

Description:

Five Finger Disposable Vinyl Glove

Sizes:

S/7- GL-TF-PVC
M/8- GL-TF-PVC
L/9- GL-TF-PVC
XL/10- GL-TF-PVC

Classification:

EN ISO 374-1:2016 Type C	Level	EN 374-4:2013 % degradation
40% Sodium hydroxide (K)	6	-16.2

EN ISO 374-5:2016
Protection against bacteria and fungi – Pass
Protection against viruses – Pass

EN388:2016	Level
Abrasion Resistance	0
Blade Cut Resistance	0
Tear Resistance	0
Puncture Resistance	0
TDM Cut Resistance	0

Standards/Technical specifications applied:
EN ISO 374-1:2016, EN ISO 374-5:2016, EN 420: 2003+A1: 2009

Technical reports/Approval documents:
SATRA: CHM0257794/1721/SMcD/A, CHM0257794/1721/SMcD/B, SPC0259252/1726, SPC0258121/1722/2

Signed on behalf of SATRA: Anita Brennan

Anita Brennan

Pete Doughty

Date of issue: 10/07/2019

Expiry date: 05/12/2023

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 certification and product 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. 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.
8. 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.
9. SATRA Technology 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.

Test Report No. 7191212723-EEC19/01-WBH
dated 13 Aug 2019

PSB Singapore

Add value.
Inspire trust.

SUBJECT:

Testing of Power-free Gloves submitted by Jiangxi Rainbow Medical Products Co.,Ltd. on 07 Jun 2019 and 29 Jul 2019.

TESTED FOR:

Jiangxi Rainbow Medical Products Co.,Ltd.
East Side of Jianshe Road, Penghuwan Industrial Area, Pengze,
Jiujiang City, Jiangxi Province, China

TEST DATE:

07 Jun 2019 to 24 Jun 2019 and 13 Aug 2019

DESCRIPTION OF SAMPLES:

S/N	Product Description	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Disposable Vinyl Gloves (Powder Free)	Clear	RB190518	M	400	Jiangxi Rainbow Medical Products Co., Ltd

Lot size as specified by client: 35,001 to 150,000 pieces

METHOD OF TEST:

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

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

3. EN 455-3:2015 Medical glove for single use
   Part 3: Requirements and testing for biological evaluation
   - Clause 4.4 Powder-free gloves
   - Clause 4.6 Labelling

TÜV SÜD PSB

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1 Science Park Drive, #02-01
Singapore 118221

RESULTS:

Sample: Disposable Vinyl Gloves (Powder Free), Size M - Lot No.: RB190518

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	7	200	5	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)	Median Length for size M: ≥ 240	13	245	Passed
	b) Width (mm)	Median Width for size M: 95 ± 10	13	95	Passed
5	Strength a) Force at break (N)	For examination gloves: ≥ 3.6	13	4.3	Passed
	b) Force at break after challenge testing (N) 7 days at (70 ± 2)°C	For examination gloves: ≥ 3.6	13	4.4	Passed

Table 3: Results for EN 455-2:2015 Clause 7

Clause	Tests	Requirements	Results	Inferred results
7	Labelling	Manufacturers shall label the glove and/or the packaging with the date of manufacture in accordance with EN ISO 15223-1:2012 and EN 1041:2008+A1:2013. Date of manufacture is defined as the packaging date.	Comply	Passed

Table 4: Results for EN 455-3:2015 Clause 4.4

Clause	Tests	Requirements	Results	Inferred results
4.4 5.2	Powder-free gloves	For powder-free gloves: The total quantity of powder residues shall not exceed 2 mg per glove.	0.17 mg per glove	Passed

RESULTS (cont'd):

Sample: Disposable Vinyl Gloves (Powder Free), Size M - Lot No.: RB190518

Table 5: Results for EN 455-3:2015 Clause 4.6

Clause	Tests	Requirements	Results
4.6	Labelling	In addition to the labelling specified in EN 1041:2008+A1:2013 and the relevant symbols given in EN ISO 15223-1:2012, the following requirements apply:	
		a) medical gloves containing natural rubber latex shall be labelled on the packaging of at least the smallest packaging unit with the EN ISO 15223-1:2012 symbol for latex;	NA
		The labelling shall include the following or equivalent warning statement together with the symbol: '(Product) contains natural rubber latex which may cause allergic reactions, including anaphylactic responses';	NA
		b) the labelling shall include a prominent indication of whether the glove is powdered or powder-free;	Comply
		c) sterile powdered gloves shall be labelled with the following or equivalent: 'CAUTION: Surface powder shall be removed aseptically prior to undertaking operative procedures in order to minimize the risk of adverse tissue reactions';	NA
		d) for any medical glove containing natural rubber latex the product labelling shall not include: - any term suggesting relative safety, such as low allergenicity, hypoallergenicity or low protein; - any unjustified indication of the presence of allergens;	NA
		e) if the manufacturer labels the gloves with the protein content, the process limit, measured as specified in 5.3 shall be given.	NA
			Inferred results: Passed

REMARKS:

NA: Not applicable as the feature was not found on sample.

Lee Dai Yi
Engineer

Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:

Photo: Disposable Vinyl Gloves (Powder Free), Size M - Lot No.: RB190518

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.

3. Nothing in this report shall be interpreted to mean that TÜV SÜD PSB has verified or ascertained any endorsement or marks from any other testing authority or bodies that may be found on that sample.

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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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11821-01-00

TÜV SÜD
Product Service

Certificate

No. Q6 105935 0001 Rev. 00

Holder of Certificate: [redacted]

Facility(ies): [redacted]
CHINA

Certification Mark:

Scope of Certificate: **Production and Distribution of Medical examination glove**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: GZ1943101

Valid from: 2020-03-02
Valid until: 2023-03-01

Date, 2020-03-02

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH · Certification Body · Ridlerstraße 65 · 80339 Munich · Germany

TÜV®

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