

PRODUCT SPECIFICATION

SECTION I: PRODUCT DESCRIPTION

| | | |
|-----|--------------------|---|
| 1.1 | Product Code | LEGPFTPC50 |
| 1.2 | Type | Nitrile - non sterile Gloves |
| 1.3 | Material | Natural High Grade Rubber Nitrile |
| 1.4 | Color | Blue |
| 1.5 | Design and Feature | <u>Ambidextrous</u> , beaded cuff, Textured |
| 1.6 | Powder content | Below 2 mg per glove |
| 1.7 | Storage Condition | The gloves shall maintain their properties when stored in a dry condition at temperature between 10° to 30° C. Avoid direct sunlight. |
| 1.8 | Shelf-Life | The gloves shall have shelf life of 5 years from the date of manufacture with the above storage condition. |
| 1.9 | Packing Style | (A) 100pcs/box, 10 boxes/carton, 1700 cartons/20°GP, 3400 cartons/40°GP (B) 2000pcs/Black Plastic Bag/Sack, 1569bags/20°GP, 2550bags/40°GP |

SECTION II: PERFORMANCE REQUIREMENTS

(Sampling Plan – ISO 2859 Single Normal)

| # | Characteristics | Inspection Level | Acceptable Quality Level | Reference Standard |
|------|--|--------------------------|--------------------------|-----------------------------------|
| 2.1 | Dimensions | Median of 13 test pieces | | EN455-2-00 |
| 2.2 | Physical Properties | Median of 13 test pieces | | EN455-2-00 |
| 2.3 | Freedom from holes (Barrier) (1000ml Water Leak Test) | GI | 2.5 | EN455-1-00 |
| 2.4 | Visual Defects: | | | |
| (i) | Major Visual | GI | 2.5 | In-house practice |
| (ii) | Minor Visual | | 4.0 | |
| 2.5 | Powder Amount | N=2 | N/A | ASTM D3578-01 ASTM D6124-00 |
| 2.6 | Protein Content | N=3 | N/A | ASTM D3578-01 ASTM D5712-95/99 |

SECTION III: PERFORMANCE SPECIFICATION

3.1 Dimensions

| Property | Size | In-House Standard |
|--------------------------------|-----------|---|
| Length (mm) | All Sizes | Min 240 |
| Average Palm Width (mm) | XS | 70 +/- 10 |
| | S | 80 +/- 10 |
| | M | 95 +/- 10 |
| | L | 110 +/- 10 |
| | XL | 120 +/- 10 |
| Thickness (mm) *single wall | | Finger : Min 0.09 Palm : Min 0.08 Cuff : Min 0.07 |
| Unit Weight (gram) | XS | 4.0 +/- 0.3 |
| | S | 4.5 +/- 0.3 |
| | M | 5.0 +/- 0.3 |
| | L | 5.5 +/- 0.3 |
| | XL | 6.0 +/- 0.3 |

3.2 Physical Properties

| Property | In-House Standard | |
|-----------------------------------|-------------------|-------------|
| | Before Aging | After Aging |
| Elongation at break (%) - Average | Min 650 | Min 500 |
| Tensile Strength (MPa) - Average | Min 18 | Min 14 |
| Stress at 500% Elongation (MPa) | Max 5.5 | NIL |

3.3 Freedom from Holes (Barrier) (1000ml Water Leak Test)

The sample size and allowable number of non-conforming gloves in the samples shall be determined in accordance to Sampling Plan ISO2859-1 Single Normal using inspection and acceptable quality level as stated in Section II: Performance Requirements.

3.4 Visual Defects

The sample size and allowable number of non-conforming gloves in the samples for both major and minor defects shall be determined in accordance to Sampling Plan ISO2859-1 Single Normal using Inspection and acceptable quality level as stated in Section II: Performance Requirements.



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实验室
CNAS L4577

TEST REPORT

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Report No.: S180201178_1

08 February 2018

APPLICANT: Tan Sin Lian Industries SDB.BHD
1-14, Jalan Indah 2
Taman Indah, 84000 Muar, Johor
Email: tsl@tansinlian.com
Phone: +606-9510 526
Malaysia

Date of receipt : 02 Feb. 2018
Testing period : 02 Feb. 2018
: 07 Feb. 2018

Buyer: ---

Sample description: Nylon/polyester liner with nitrile pain coated, Sandy finish.

Style / Article no. : 0NM454/3518

Test(s) requested : ---

Service : REGULAR

Brand / Section : ---

Season : ---

End use : ---

Factory name : ---

Factory code : ---

For OE Marking : Yes

Previous report : ---

Product category : ---

Product type : ---

Test stage : FIRST TEST

Supplier name : ---

Exported to : ---

1. Conclusion:

| | Tests description | Conformity |
|---|---|------------|
| 1 | 4.3.2. pH - Textile (KCl solution) : EN ISO 3071:2006 | Pass |
| 2 | 5.1.2. Sizing : EN 430:2003+A1:2009 | None |
| 3 | 5.2. Density : EN 430:2003+A1:2009 | Level 5 |
| 4 | Alkylphenols - Textile : ISO 18254-1: 2015 | None |
| 5 | Azo dyes - Textile : EN 14362-1 : 2012 | Pass |
| 6 | Polycyclic Aromatic Hydrocarbons : ISO/TS 15190: 2013 | Pass |
| 7 | XRF screening : ASTM F 3517-15 | Pass |

Pass: requirements met Fail: requirements not met None: no requirement for this test N/A: not applicable

Approved by

Henry YAN
Laboratory Manager

Tony SHU
Chemical lab supervisor

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CNAS has accredited the laboratory under the China National Accreditation Scheme (CNAS) for specific laboratory activities as listed in the CNAS directory of accredited laboratories. The results shown in this report were determined by the laboratory in accordance with its terms of accreditation.

SGS

Certificate TH10/4860

The management system of

TAN SIN LIAN INDUSTRIES SDN. BHD

1-14, Jalan Indah 2
Taman Indah, 84000 Muar, Johor
Malaysia

Has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities

Manufacture of non-sterile powdered natural latex examination gloves
Manufacture of non-sterile powdered free natural latex examination gloves
Manufacture of non-sterile nitrile examination gloves
Distribution of natural latex and synthetic examination gloves

Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2015 requirements may be obtained by consulting the organisation

This certificate is valid from 25 June 2019 until 25 June 2022 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 7 May 2022

Issue 6. Certified since 25 June 2010

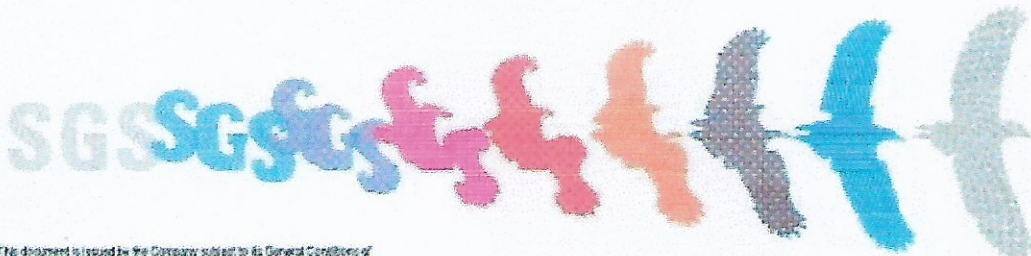
Authorised by



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EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60128541 0001

Report No.: 16806956 002

Manufacturer: TAN SIN LIAN INDUSTRIES SDN.
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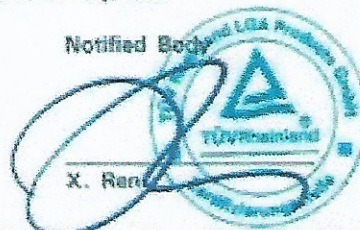
Products: Not Sterile Nitrile Examination Gloves
Replaces Approval, Registration No.: DD 60124276 0001

Expiry Date: 2022-11-01

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2018-05-02

Date: 2018-05-02



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.