

SRI TRANG GLOVES (THAILAND) PUBLIC COMPANY LIMITED

10 Soi 10 Phetkasem Rd., Hatyai, Songkhla, Thailand, 90110

Tel. (66) 074-344-663 Fax. (66) 074-344-677

SCT.PD.SP.05.175-200719 R.00

DAR-SCT-2019-0452

TECHNICAL PRODUCT-DESCRIPTION

FILE NO: US-LCM-T

Latex Powder Free, Offline Chlorination Gloves, Medical US Spec

PAGE 1 of 3

PRODUCT

Latex Examination Glove, powder free, inner coating

Medical grade, Textured surface, Non-sterile

INTENDED USE

Medical activities on the outer, intact skin of the body, including all natural orifices.

MATERIAL

Natural rubber latex

Warning: This product contains natural rubber latex which may cause allergic reactions.

SURFACE TREATMENT

No donning powder is used.

Halogenation / siliconization and extensive washing in water.

Inside coated with synthetical material

SHAPE

Straight fingers, thumb and fingers in one plane, fits either hand (ambidextrous)

Rolled rim

SIZES

Extra small (XS), Small (S), Medium (M), Large (L), Extra-large (XL)

COLOR

According to the appendix

MARKING

Gloves are not marked to designated size

Vigilance and Reporting system

Conducted according to the official reporting criteria of problems and reactions, caused by examination gloves must be reported within one day by phone or fax.

1. To Sri Trang Agro-Industry Public Company Limited (Bangkok Branch). Contact to: Marketing Manager (Tel :+66 2207 4500 Ext 2402 Fax: 66 2108 2241 44)
2. To Sri Trang USA, Inc. Contact to: Quality Assurance and Regulatory Affairs Leader (Tel: Direct: +1 (813) 606-4316 | TF: +1 (888) 483-6898)
3. To Sri Trang Gloves (Thailand) Public Company Limited Contact to: Product Manager (Tel:+66 74 291 648, Fax: 291 650).

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QUALITY CHARACTERISTICS (Every mentioned standard is used in the latest edition.)

US: American standard/requirement

DESCRIPTION	SPECIFICATION	TEST-METHOD
BIOCOMPATIBILITY		
Powder residue on powder free gloves	≤ 2.0 mg/glove	ASTM D 6124
Total Proteins	< 50 μ g/g	Monitoring follows ASTM D 5712
PHYSICAL PROPERTIES	ASTM D 3578	
Tensile strength before/after aging (MPa)	Min 18 / 14 MPa	ASTM D 412/ ASTM D 573
Ultimate elongation before/ after aging (%)	Min 650% / 500%	ASTM D 412 /ASTM D 573
DIMENSION	ASTM D 3578	ASTM D 3767
Hand-width size related	Size related table issued on request XS : 70 ± 10 mm. S : 80 ± 10 mm. M : 95 ± 10 mm. L : 111 ± 10 mm. XL : ≥ 111 mm.	
Total length	ASTM D 3578 Min 220 mm: XS, S Min 230 mm: M, L, XL	ASTM D 3767
Single Wall thickness	ASTM D 3578	ASTM D 3767
Finger	Min 0.08 mm.	
Palm	Min 0.08 mm.	

FINAL GLOVE RELEASE PACKAGING; MARKING; CONTAINER DELIVERY INSPECTION

Assurance action following the latest edition of the standards

ASTM D 3578 "Standard Specification for Rubber Examination Gloves"

Set-up and patrol inspection (in process) at packaging and labelling.

Supervision and stuffing records of vehicle or vessel loading.

PERFORMANCE REQUIREMENTS FOR QUALITY CHARACTERISTICS

In accordance with ISO 2859-1 "Sampling Procedures and Tables for Inspection by Attribute".

All standards listed in this specification are applied to medical gloves non-sterile.

PRODUCTION ATTRIBUTIVE RELEASE INSPECTION

Sampling for inspection in accordance with ISO 2859-1 (unit 1 glove).

GOOD MANUFACTURING PRACTICE

The gloves are manufactured in compliance with ISO 9001, ISO 13485.

MICROBIOLOGICAL CLEANNES CONTROL

The bioburden of the finished gloves are monitored and recorded. Unusual contaminants are identified. It is attempted to determine their sources and eliminating or reducing their impact. Tests are performed by an approved Institute for Microbiological Control.

CAUTION: Non-sterile examination gloves are used in a variety of circumstances, including procedures where the surface of the glove contacts wounds, body cavities, or other possible routes of contamination.

CERTIFICATES

A Certificate of Compliance with this specification can be issued only on request together with the order.

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PAGE 3 of 3

STORAGE

Keep storage area cool, dry and dust free, avoid ventilation and storage close to photocopy equipment. Copper ions discolour the glove. Protect gloves against ultraviolet light sources, as sunlight and oxidizing agents. Storage above 100°F(38°C) will lead to accelerated aging and should be avoided under any circumstances. Long term storage in bulk can lead to pleats, stickiness and early aging of the glove and should be avoided.

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Appendix of Specification

APPENDIX: 1

US-LCMC-1T

Revision: 1

SAMPLING, INSPECTION AND FINAL RELEASE INFORMATION

Product Specification Code	Glove color	Characteristics		Test-Method
		Major defects*	Minor defects*	
US-LCMC-1T	Natural - white	AQL \leq 1.5	AQL \leq 4.0	ASTM D 5151

Major defects:

Pinholes enclosed - Inspection level G I for leaks, highest concern are non-conformities which prevent correct use of the product.

Minor defects:

Inspection level G I for visual defects aggregated are non-conformities of lower degree of concern, which do not prevent correct use of gloves.

Remark:

* Test-Method following In-house practice.