

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.05.491-150719 R.00

DAR-SCT-2019-0768

TECHNICAL PRODUCT-DESCRIPTION

FILE NO: US-NCM-FE

Nitrile Powder Free, Offline Chlorination Gloves, Medical US Spec

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PRODUCT

Nitrile Examination Glove, powder free, inner coating

Medical grade, Textured at Finger Tip surface, Non-sterile

INTENDED USE

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

MATERIAL

Nitrile latex. This product does not contain Proteins found in Natural Rubber goods.

SURFACE TREATMENT

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
PHYSICAL PROPERTIES	ASTM D 6319	
Tensile strength before/after aging (MPa) Ultimate elongation before/ after aging (%)	Min 14 / 14MPa 500% / 400%	ASTM D 412/ ASTM D 573 ASTM D 412 /ASTM D 573
DIMENSION Hand-width size related	ASTM D 6319 size related table issued on request XS : 70±10 mm. S : 80 ± 10 mm. M : 95 ± 10 mm. L : 110 ± 10 mm. XL : 120 ± 10 mm.	ASTM D 3767
Total length	ASTM D 6319 Min 220 mm: XS, S Min 230 mm: M, L, XL	ASTM D 3767
Single Wall thickness	ASTM D 6319	ASTM D 3767
Finger Palm	Min 0.05 mm. Min 0.05 mm.	

FINAL GLOVE RELEASE PACKAGING; MARKING; CONTAINER DELIVERY INSPECTION

Assurance action following the latest edition of the standards

ASTM D 6319 "Standard Specification for Nitrile Examination Gloves for Medical Application"

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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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 : 4

US-NCMC-15FE

Revision: 1

SAMPLING, INSPECTION AND FINAL RELEASE INFORMATION

Product Specification Code	Glove color	Characteristics		Test-Method
		Major defects*	Minor defects*	
US-NCMC-15FE	Black	AQL <= 1.5	AQL <= 4.0	ASTM D5151

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.