



# Certificate

No. Q5 099188 0004 Rev. 05

**Holder of Certificate:** **Sri Trang Gloves (Thailand)  
Public Company Limited**  
10 Soi 10, Phetkasem Road  
Hat Yai, Songkhla 90110  
THAILAND

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production and  
Distribution of Sterile and Non-sterile  
Examination Gloves**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 099188 0004 Rev. 05](http://www.tuvsud.com/ps-cert?q=cert:Q5 099188 0004 Rev. 05)

**Report No.:** MYQMH0620098Rev1-721425589

**Valid from:** 2021-05-01  
**Valid until:** 2023-10-31

**Date,** 2021-04-23

Christoph Dicks  
Head of Certification/Notified Body

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## Applied Standard(s):

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

## Facility(ies):

Sri Trang Gloves (Thailand) Public Company Limited  
110 Kanjanavanit Road, Pahtong, Hat Yai, Songkhla 90230,  
THAILAND

Design and Development, Production and Distribution of Sterile  
and Non-sterile Examination Gloves

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Design and Development, Production and Distribution of Sterile  
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THAILAND

Design and Development, Production and Distribution of Sterile  
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THAILAND

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189, Moo 7, Phlai Wat, Kanchanadit, Surat Thani 84160,  
THAILAND

Design and Development, Production and Distribution of Sterile  
and Non-sterile Examination Gloves

Sri Trang Gloves (Thailand) Public Company Limited  
85 Moo 6, Khuan Thani, Kantang, Trang 92110, THAILAND

Design and Development, Production and Distribution of Sterile  
and Non-sterile Examination Gloves

# 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.05.237-220421 R.03  
PRODUCT SPECIFICATION SHEET : LXXOGF-B-EU-M-NS

DAR-SCT-2021-0543  
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## GLOVE SPECIFICATION

**Product Specification Group Code :** LXXOGF-B-EU-M-NS  
**Product Code :** DLXFBOG  
**Product name :** Latex Examination Gloves, Powdered, Non Sterile  
**Grade :** EU Spec, Medical Grade

### GENERAL INFORMATION


**Type :** Single-use disposable examination or protective glove  
**Marking :** Gloves are not marked to designated size.  
**Shape :** Ambidextrous  
**Material :** Natural Rubber  
**Cuff :** Rolled cuff  
**Surface :** Textured at Finger Tip

<b>Thickness :</b> (single wall according to ASTM D3578, ASTM D3767)		<b>Finger :</b> Min. 0.08mm	<b>Palm :</b> Min. 0.08mm
<b>Residual powder :</b> (according to EN 455-3, EN ISO 21171)	Max. 10mg/dm2	<b>Force at break :</b> (according to EN 455-2)	Before Aging : Med. ≥ 6.0N After Aging : Med. ≥ 6.0N
<b>Protein content :</b> (according to EN 455-3)	Max. 150ug/g	<b>Tensile Strength :</b> (according to ASTM D3578, ASTM D412, ASTM D573)	Before Aging : Min. 18Mpa After Aging : Min. 14Mpa
<b>Length :</b> (according to EN 455-2)	XS-XL : Med. ≥ 240mm	<b>% Elongation :</b> (according to ASTM D3578, ASTM D412, ASTM D573)	Before Aging : Min. 650% After Aging : Min. 500%
<b>Available Sizes &amp; Palm width (mm) :</b> XS (5-6) : ≤ 80, S (6-7) : 80+/-10, M (7-8) : 95 +/-10, L (8-9) : 110+/-10, XL (9-10) : ≥ 110 (according to EN 455-2)			

**Storage:** 5 years storage life (date of expiration see on the box). Keep area cool, dry and dust free, avoid ventilation and storage close to photocopy equipment. Copper-ions discolor the glove. Protect gloves against ultraviolet light sources, as sunlight and oxidizing agents. Storage above 30°C will lead to accelerated aging and should be avoided.

### STANDARDS, GUIDELINES AND QUALITY CERTIFICATION

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

<b>Certification :</b>	ISO 9001, ISO 13485		
<b>Conformity to guidelines :</b>	Medical Device Regulation (EU)2017/745 : Class I under Rule1 and Rule 5 according to Annex VIII (Subject to EU Declaration of Conformity to brand owner)		
	Personal Protective Equipment Regulation (EU) 2016/425 : Category I or Category III (Subject to EU Type-Examination Certificate)		
<b>Conformity to standards :</b>	<u>Medical</u>	<u>PPE</u>	<u>PPE</u>
	EN 455	CAT I	CAT III
	ASTM D3578	EN 420	EN 420
			EN 374
			EN 16523-1
<b>Conformity to food regulation :</b>	1935/2004		

### WARNING AND REPORTING SYSTEM

**Potentially allergenic Ingredients :** Dithiocarbamate type.  
(For further information, the actual version of the ingredients list is given on request.)

Please report any incidents with the products to **STGT\_TA@srtranggroup.com** and **regulatory@srtranggroup.com** without undue delay. Our Product Safety Officers will review all information provided and might contact the original informant for further clarification.

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PRODUCT SPECIFICATION SHEET : LXXOGF-B-EU-M-NS

DAR-SCT-2021-0543

Appendix of specification

## APPENDIX : 2

**Product Specification Code :** LXXOGF-B-WHT-EU-MC-NS  
**Product Code :** DLXFBOG  
**Material :** Natural Rubber  
**Treatment and Feature :** Corn Starch Powder (Absorbable Dusting Powder-USP Grade)

## SAMPLING, INSPECTION AND FINAL RELEASE INFORMATION

Product Specification Code	Glove color	Characteristics			Test-Method
		Barrier Defects*	Major Visual Defects*	Minor Defects*	
LXXOGF-B-WHT-EU-MC-NS	WHITE	AQL ≤ 1.5	AQL ≤ 1.5	AQL ≤ 4.0	EN 455-1

### Barrier Defects :

Inspection level G I (ISO 2859-1)

Holes that results in the malfunction of glove as a protection barrier either physically or not physically affect the appearance.

### Major Visual Defects :

Inspection level G I (ISO 2859-1)

Defined defect that disrupt the glove's function or defect that cause an uncomfortable feeling to the user.

### Minor Defects :

Inspection level G I (ISO 2859-1)

Visual defects aggregated are non-conformities of lower degree of concern, which do not prevent correct use of gloves. Minor cosmetic defect which does not affect on the glove's performance

Remark :

\* Defect Characteristics following In-house practice.