



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

Certificate

No. Q5 099188 0004 Rev. 05

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

Sri Trang Gloves (Thailand) Public Company Limited
109/2 Kanjanavanit Road, Pahtong, Hat Yai, Songkhla 90230,
THAILAND

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

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

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

Sri Trang Gloves (Thailand) Public Company Limited
110/3 Kanjanavanit Road, Pahtong, Hat Yai, Songkhla 90230,
THAILAND

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

Sri Trang Gloves (Thailand) Public Company Limited
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
PAGE 1 of 1

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

Thickness : (single wall according to ASTM D3578, ASTM D3767)	Finger : Min. 0.08mm	Palm : Min. 0.08mm
---	-----------------------------	---------------------------

Residual powder : (according to EN 455-3, EN ISO 21171)	Max. 10mg/dm ²	Force at break : (according to EN 455-2)	Before Aging : Med. ≥ 6.0N After Aging : Med. ≥ 6.0N
---	---------------------------	--	---

Protein content : (according to EN 455-3)	Max. 150ug/g	Tensile Strength : (according to ASTM D3578, ASTM D412, ASTM D573)	Before Aging : Min. 18Mpa After Aging : Min. 14Mpa
---	--------------	--	---


Length : (according to EN 455-2)	XS-XL : Med. ≥ 240mm	% Elongation : (according to ASTM D3578, ASTM D412, ASTM D573)	Before Aging : Min. 650% After Aging : Min. 500%
--	----------------------	--	---

Available Sizes & Palm width (mm) : 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.)

Certification :	ISO 9001, ISO 13485		
Conformity to guidelines :	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)		
Conformity to standards :	<u>Medical</u> EN 455 ASTM D3578	<u>PPE</u> CAT I EN 420	<u>PPE</u> CAT III EN 420 EN 374 EN 16523-1
Conformity to food regulation :	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@sritranggroup.com and regulatory@sritranggroup.com without undue delay. Our Product Safety Officers will review all information provided and might contact the original informant for further clarification.

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

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.