

# 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/dm <sup>2</sup>	<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> EN 455 ASTM D3578	<u>PPE</u> CAT I EN 420	<u>PPE</u> CAT III 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@sritranggroup.com](mailto:STGT_TA@sritranggroup.com) and [regulatory@sritranggroup.com](mailto:regulatory@sritranggroup.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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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.