

SRI TRANG GLOVES (THAILAND) PUBLIC COMPANY LIMITED

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SCT.PD.SP.05.237-220421 R.03
PRODUCT SPECIFICATION SHEET : LXXOGF-B-EU-M-NS

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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

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

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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.