SRI TRANG GLOVES (THAILAND) PUBLIC COMPANY LIMITED

10 Soi 10 Phetkasem Road, Hat Yai, Hat Yai, Songkhla 90110 Thailand Tel. (66) 074-344-663 Fax. (66) 074-344-677

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

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

Warning: This product contains natural rubber latex which may cause allergic reactions

Cuff: Rolled cuff

Surface: **Textured at Finger Tip**

Thickness:

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

(according to EN 455-3,

Powder amount:

EN ISO 21171)

Max. 10mg/dm²

Protein content:

Max. 150µg/g (according to EN 455-3)

Length:

(according to EN 455-2)

XS-XL: Med. ≥ 240mm

Before Aging: Med. ≥ 6.0N Force at break:

(according to EN 455-2) After Aging : Med. ≥ 6.0N

Tensile Strength: Before Aging: Min. 18Mpa

(according to ASTM D3578, After Aging : Min. 14Mpa **ASTM D412, ASTM D573)**

% Elongation: Before Aging: Min. 650%

(according to ASTM D3578, After Aging : Min. 500% **ASTM D412, ASTM D573)**

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

Medical Device Regulation (EU)2017/745: Class I under Rule1 and Rule 5 according to Annex Conformity to guidelines:

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: PPE Medical PPE

> EN 455 CATI CAT III

ASTM D3578 EN ISO 21420 EN ISO 21420

> **EN ISO 374** EN 16523-1

577 Conformity to food regulation: 1935/2004

WARNING AND REPORTING SYSTEM

Dithiocarbamate type. Potentially allergenic ingredients:

(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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PRODUCT SPECIFICATION SHEET: LXXOGF-B-EU-M-NS 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		Test-Method		
Product Specification Code	GIOVE COIOI	Barrier Defects*	Major Visual Defects*	Minor Defects*	rest-metriou
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.

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L						EXP:			YYYY-MM(MFG+	SYRS)	
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