

SRI TRANG GLOVES (THAILAND) PUBLIC COMPANY LIMITED

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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 : LXFBOG

Product name : Latex Examination Gloves, Powdered, Non Sterile, 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. 10 mg/dm ²
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Force at break : (according to EN 455-2)	Before Aging : Med. \geq 6.0N After Aging : Med. \geq 6.0N
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Protein content : (according to EN 455-3)	Max. 150ug/g
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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. \geq 240mm
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% 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) : According to EN 455-2

XS (5-6) : \leq 80, S (6-7) : 80+/-10, M (7-8) : 95 +/-10, L (8-9) : 110+/-10, XL (9-10) : \geq 110

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
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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.