

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

SCT.PD.SP.05.237-100322 R.05

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

DAR-SCT-2022-0410

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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
Warning: This product contains natural rubber latex which may cause allergic reactions
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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Powder amount : (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. 150µg/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 ISO 21420	<u>PPE</u> CAT III EN ISO 21420 EN ISO 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.

Product description / Details of packaging for Change Control No.:				OTC-STA-0821-1734	
1. Brand Name:		SRITRANG		Customer : IMUNOTEHNOMED(MOLDOVA)	
Brand Name (INT):		STGEUVRH-10X100-LXFBOG-EUC-WHT-NS-BX			
2. Product Type:		LATEX POWDERED WHITE TEXTURED AT FINGER TIPS NON-STERILE			
3. KMAT :		DLXFBOG		510K No.: -	
Specification:		LXXOGF-B-WHT-EU-MC-NS		CA No.: -	
4. Material number (FG):					
Size XS :		14018223		Size L : 14018226	
Size S :		14018224		Size XL : 14018227	
Size M :		14018225		Size 2L : -	
5. Packaging					
Packaging type : INNER BOX					
Dimension(mm): PKGPD03		W: 110	L: 200	H: 60	
SIZE	COLOR	MATERIAL NO.(PCK)	VERSION		
FS	BLACK,2577C	20017865	C01		
XS					
S					
M					
L					
XL					
2L					
Packaging type : OUTER BOX					
Dimension(mm): PKGPD03		W: 225	L: 310	H: 210	
SIZE	COLOR	MATERIAL NO.(PCK)	VERSION		
FS	BLACK,2577U	20017866	C01		
XS					
S					
M					
L					
XL					
2L					
Packaging type : -					
Dimension(mm): -		W: -	L: -	H: -	
SIZE	COLOR	MATERIAL NO.(PCK)	VERSION		
FS	-	-	-		
XS	-	-	-		
S	-	-	-		
M	-	-	-		
L	-	-	-		
XL	-	-	-		
2L	-	-	-		
Packaging type : -					
Dimension(mm): -		W: -	L: -	H: -	
SIZE	COLOR	MATERIAL NO.(PCK)	VERSION		
FS	-	-	-		
XS	-	-	-		
S	-	-	-		
M	-	-	-		
L	-	-	-		
XL	-	-	-		
2L	-	-	-		

Material: DUPLEX		FSC: NO
Flap: LOCKING	Coating: VARNISHING	
Opening:	OTHER AND NON STD-SINGLE LINE	
Marking Size by:	TICK SIZE BY BLACK	
MFG+Lot No.:	YYYY-MM(MFG) XXXX(INT) CCCC(CASE) DLXFBOG(SPECIAL)	
MFG:	-	
EXP :	YYYY-MM(MFG+5YRS)	
Pre-print:	NO	
Remark:	Shared artwork with STGEUVRH-10X100-LXFBOG-EUC-WHT-NS-BX Inkjet DLXFBOG behind (CASE NO.)	
Material: B.BROWN		FSC: NO
Flap: -	Coating: -	
Opening:	-	
Marking Size by:	STAMP TEXT BY BLACK	
MFG+Lot No.:	YYYY-MM(MFG) XXXX(INT) CCCC(CASE).REF.DLXFBOG(SPECIAL)	
MFG:	-	
EXP :	YYYY-MM(MFG+5YRS)	
Pre-print:	NO	
Remark:	Shared artwork with STGEUVRH-10X100-LXFBOG-EUC-WHT-NS-BX Inkjet. REF. DLXFBOG short side 2	
Material: -		FSC: -
Flap: -	Coating: -	
Opening:	-	
Marking Size by:	-	
MFG+Lot No.:	-	
MFG:	-	
EXP :	-	
Pre-print:	-	
Remark:	-	
Material: -		FSC: -
Flap: -	Coating: -	
Opening:	-	
Marking Size by:	-	
MFG+Lot No.:	-	
MFG:	-	
EXP :	-	
Pre-print:	-	
Remark:	-	

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6. Packing/Contain instructions.

Dispenser
 Carton
 Packing Method

☐ Use ☒ Not Use Plastic under the perforation of dispenser boxes
☐ Use ☒ Not Use Plastic bag for dispenser boxes - -
☐ Use ☒ Not Use Poly bag for carton Color: -

7. Loading quantity

Container 20ft : Cartons / Container 40ft : Cartons / Container 40ftHC : Cartons / Truck : Cartons

8. Change description

For Dispenser box :

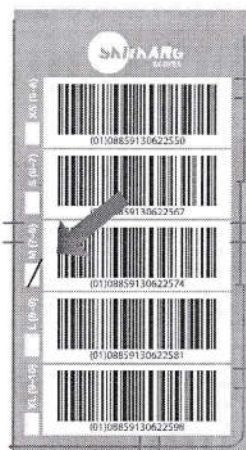
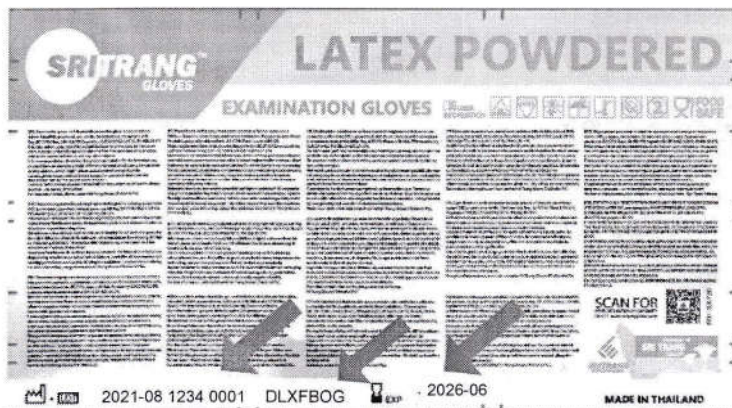
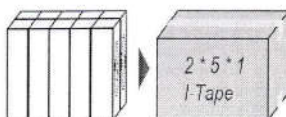
-Change format inkjet
 -Shared artwork with STGEUVRH-10X100-LXFBG-EUC-WHT-NS-BX

For Transport carton :

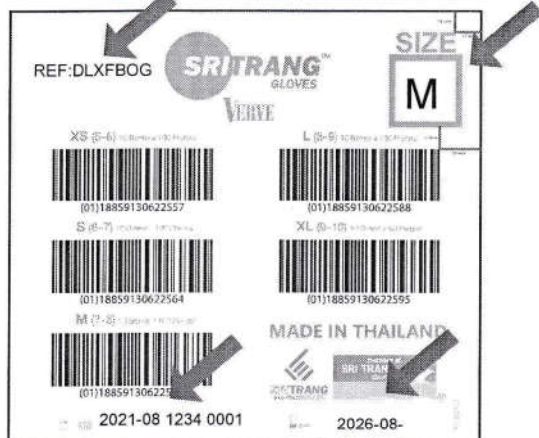
-Change format inkjet
 -Shared artwork with STGEUVRH-10X100-LXFBG-EUC-WHT-NS-BX

9. Packing format and Inkjet format

Special format : (Packing Format : Outer / Special Ink-Jet)



INKJET BY STGT INTERNAL DEPT.



St.B.