

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.05.035-010622 R.05

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

DAR-SCT-2022-0614

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GLOVE SPECIFICATION

Product Specification Group Code : LOOOGF-B-EU-M-NS
Product Code : DLOFBOG
Product name : Latex Examination Gloves, Powder Free, Chlorinated, 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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Residual powder : (according to EN 455-3, EN ISO 21171)	Max. 2.0mg/glove
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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. 50 μ g/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) : 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 :	<table><tr><td><u>Medical</u></td><td><u>PPE</u></td><td><u>PPE</u></td></tr><tr><td>EN 455</td><td>CAT I</td><td>CAT III</td></tr><tr><td>ASTM D3578</td><td>EN ISO 21420</td><td>EN ISO 21420</td></tr><tr><td></td><td></td><td>EN ISO 374</td></tr><tr><td></td><td></td><td>EN 16523-1</td></tr></table>	<u>Medical</u>	<u>PPE</u>	<u>PPE</u>	EN 455	CAT I	CAT III	ASTM D3578	EN ISO 21420	EN ISO 21420			EN ISO 374			EN 16523-1
<u>Medical</u>	<u>PPE</u>	<u>PPE</u>														
EN 455	CAT I	CAT III														
ASTM D3578	EN ISO 21420	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 stgt_tp@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 : LOOOGF-B-WHT-EU-MC-NS
Product Code : DLOFBOG
Material : Natural Rubber
Treatment and Feature : Powder Free, Online Chlorinated

SAMPLING, INSPECTION AND FINAL RELEASE INFORMATION

Product Specification Code	Glove color	Characteristics			Test-Method
		Barrier Defects*	Major Visual Defects*	Minor Defects*	
LOOOGF-B-WHT-EU-MC-NS	WHITE (PALE YELLOW)	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-0821-1675

1. Brand Name:	SRITRANG	Customer:	IMUNOTEHNOMED(MOLDOVA)
Brand Name (INT):	STGEUVVH-10X100-LOFBOG-EUC-WHT-NS-BX		
2. Product Type:	LATEX POWDER FREE WHITE TEXTURED AT FINER TIPS NON-STERILE		
3. KMAT:	DLOFBOG	510K No.:	-
Specification:	LOOOGF-B-WHT-EU-MC-NS	CA No.:	-

4. Material number (FG):

Size XS :	14019467
Size S :	14019468
Size M :	14019469

Size L :	14019470
Size XL :	14019471
Size 2L :	-

5. Packaging

Packaging type :	INNER BOX
Dimension(mm):	PKGPF02 W: 122 L: 240 H: 65

SIZE	COLOR	MATERIAL NO.(PCK)	VERSION
FS	BLACK,369C	05012002301304443 (20014203)	C00
XS			
S			
M			
L			
XL			
2L			

Packaging type :	OUTER BOX
Dimension(mm):	PKGPF02 W: 249 L: 340 H: 250

SIZE	COLOR	MATERIAL NO.(PCK)	VERSION
FS	BLACK,369U	05011002301303744 (20014204)	C00
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
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Flap:	LOCKING	Coating:	VARNISHING
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Opening:	OTHER AND NON STD-SINGLE LINE
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Marking Size by:	TICK SIZE BY BLACK
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MFG+Lot No.:	YYYY-MM(MFG) XXXX(INT) CCCC(CASE) DLOFBOG(SPECIAL)
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MFG:	-
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EXP :	YYYY-MM(MFG+3YRS)
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Pre-print:	NO
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Remark:	Share artwork with : TGEUVVH-10X100-LOFBOG-EUC-WHT-NS-BX Inkjet "DLOFBOG" behind (CASE NO.)
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Material:	B,BROWN	FSC:	NO
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Flap:	-	Coating:	-
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Opening:	-
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Marking Size by:	STAMP TEXT BY BLACK
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MFG+Lot No.:	YYYY-MM(MFG) XXXX(INT) CCCC(CASE) REF:DLOFBOG(SPECIAL)
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MFG:	-
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EXP :	YYYY-MM(MFG+3YRS)
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Pre-print:	NO
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Remark:	Share artwork with : TGEUVVH-10X100-LOFBOG-EUC-WHT-NS-BX Inkjet REF:DLOFBOG short side 2
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Material:		FSC:	
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Flap:		Coating:	
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Opening:	
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Marking Size by:	
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MFG+Lot No.:	
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MFG:	
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EXP :	
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Pre-print:	
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Remark:	
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Material:		FSC:	
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Flap:		Coating:	
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Opening:	
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Marking Size by:	
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MFG+Lot No.:	
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MFG:	
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EXP :	
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Pre-print:	
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Remark:	
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6. Packing/Contain instructions.

Dispenser Approx. 100(XL:90) pcs by weight/dispenser box.

☐ Use ☒ Not Use Plastic under the perforation of dispenser boxes

Carton 10 Dispenser boxes./ Carton.

☐ Use ☒ Not Use Plastic bag for dispenser boxes

Packing Method LAYER

☐ Use ☒ Not Use Poly bag for carton Color:

7. Loading quantity

Container 20ft : 1392 Cartons / Container 40ft : 2838 Cartons / Container 40ftHC : 3220 Cartons / Truckt : Cartons

8. Change description

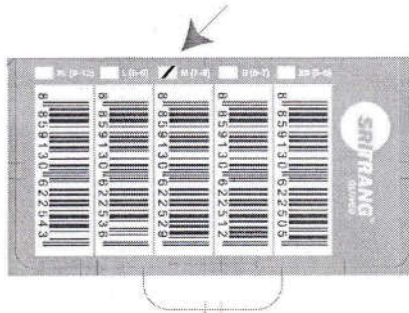
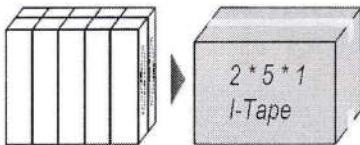
For Dispenser box :

Add customer IMUNOTEHNOMED(MOLDOVA) under brand :
STGEUVVH-10X100-LOFBOG-EUC-WHT-NS-BX
Share artwork with brand STGEUVVH-10X100-LOFBOG-EUC-WHT-NS-BX
(NEXTECH(TURKEY) CUSTOMER)

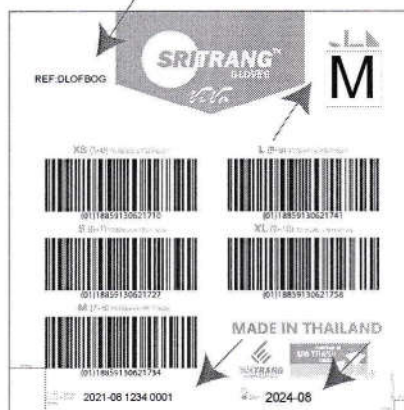
For Transport carton :

Add customer IMUNOTEHNOMED(MOLDOVA) under brand :
STGEUVVH-10X100-LOFBOG-EUC-WHT-NS-BX
Share artwork with brand STGEUVVH-10X100-LOFBOG-EUC-WHT-NS-BX
(NEXTECH(TURKEY) CUSTOMER)

9. Packing format and Inkjet format



INKJET BY STGT INTERNAL DEPT.



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