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 DAR-SCT-2022-0614 PRODUCT SPECIFICATION SHEET: LOOOGF-B-EU-M-NS PAGE 1 of 1

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:

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

Residual powder:

(according to EN 455-3, EN ISO 21171)

Max. 2.0mg/glove

Protein content:

(according to EN 455-3)

Max. 50µg/g

Length:

(according to EN 455-2)

XS-XL: Med. ≥ 240mm

Force at break:

(according to EN 455-2)

Tensile Strength:

(according to ASTM D3578, **ASTM D412, ASTM D573)**

% Elongation:

(according to ASTM D3578. **ASTM D412, ASTM D573)**

Before Aging: Min. 650%

Before Aging: Med. ≥ 6.0N

After Aging : Med. ≥ 6.0N

Before Aging: Min. 18Mpa

After Aging : Min. 14Mpa

After Aging : Min. 500%

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 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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DAR-SCT-2022-0614

SCT.PD.SP.05.035-010622 R.05

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

Ī	Braduet Specification Code	Glove color		Test-Method		
	Product Specification Code		Barrier Defects*	Major Visual Defects*	Minor Defects*	1 est-Metriod
ĺ	LOOOGF-B-WHT-EU-MC-NS	WHITE	AQL ≤ 1.5	AQL ≤ 1.5	AQL ≤ 4.0	EN 455-1
	LOOGE-B-WHI-EU-MC-N3	(PALE YELLOW)	AQL 5 1.5	AQL ≥ 1.0	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

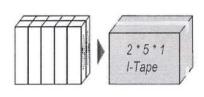
Remark:

^{*} Defect Characteristics following In-house practice.

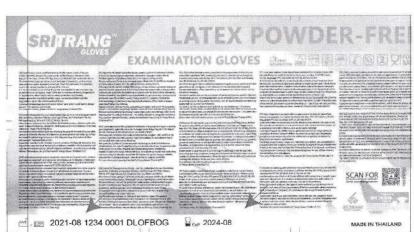
Produ	uct descripti	on / Details of pa	ckaging for Change Cont	trol No.:	OTC-STA-0821	-1675	
1. Bra	Brand Name: SRITRANG		Customer : IMUNOTEHNOMED(MOLDOVA)				
Brand Name (I		STGEUVVH	H-10X100-LOFBOG-EUC-V	VHT-NS-B			
	oduct Type:		DER FREE WHITE TEXTURE	R TIPS NON-STERIL	LE .		
		DLOFBOG			510K No.:		
LOCOCE BANET FLIMONO							
	ecification:		-WITI-EO-MO-NO		CA No.:		
1	terial numbe				[2,]	TVENE (Exc	
	Size XS : 14019467		Size L :	14019470			
		4019468			Size XL :	14019471	
Si	ze M : 1	4019469			Size 2L :	•	
5. Pac	ckaging						
acka	aging type :	INNER BOX			Material: DUP	LEX FSC: NO	
Dime	sion(mm): PKGPF02 W: 122 L: 240 H: 65						
SIZE		COLOR	MATERIAL NO.(PCK)	VERSION	Flap: LOCKING	Coating: VARNISHING	
FS	BLACK,36	9C	05012002301304443 (20014203)	C00	Opening:	OTHER AND NON STD-SINGLE LINE	
xs			7/201-0-100		Marking Size by	TICK SIZE BY BLACK	
s				The second	MFG+Lot No.:	YYYY-MM(MFG) XXXX(INT) CCCC(CASE) DLOFBOG(SPACIAL)	
м					MFG:	-	
L					EXP:	YYYY-MM(MFG+3YRS)	
XL					Pre-print:	NO NO	
2L					Remark:	Share artwork with : TGEUVVH-10X100-LOFBOG-EUC-WHT-NS-BX	
		OUTED BOY				Inkjet "DLOFBOG" behind (CASE NO.)	
	iging type :	OUTER BOX][2.2]. [2.2]		Material: B,BR	OWN FSC: NO	
	nsion(mm):		W: 249 L: 340				
SIZE		COLOR	MATERIAL NO.(PCK)	VERSION	Flap: -	Coating: -	
FS	BLACK,36	9U	05011002301303744 (20014204)	C00	Opening:	-	
XS					Marking Size by	STAMP TEXT BY BLACK	
s					MFG+Lot No.:	YYYY-MM(MFG) XXXX(INT) CCCC(CASE) REF:DLOFBOG(SPACIAL)	
M					MFG:	-	
L					EXP:	YYYY-MM(MFG+3YRS)	
XL		*			Pre-print:	NO	
2L					Remark:	Share artwork with: TGEUVVH-10X100-LOFBOG-EUC-VHT-NS-BX Inkjet REF:DLOFBOG short side 2	
acka	ging type :				Material:	FSC:	
	nsion(mm):		W: L:	н:	materiali	100.	
SIZE	ioion(min). [COLOR	MATERIAL NO.(PCK)		Flap:	Coating:	
FS		OCLOR	MAILMAL NO.(FCK)	TENSION	Opening:		
_				-	The state of the s		
xs					Marking Size by	-	
S					MFG+Lot No.:		
M				-	MFG:		
L					EXP:		
XL					Pre-print:		
2L					Remark:		
acka	ging type :				Material:	FSC:	
imen	sion(mm):		W: L: I	H:			
SIZE		COLOR	MATERIAL NO.(PCK)	VERSION	Flap:	Coating:	
FS			, ,		Opening:	mun. LTD Well	
xs					Marking Size by		
s					MFG+Lot No.:	10/15	
м					MFG:	MUNOTEHNOMEN	
					EXP:	STORY STORY OF THE	
L				-	1.00	S.R.,	
XL					Pre-print:	00260001758/23/	
2L					Remark:	A 4441	

Page 2(3)

D1	acking/Contain instructions.		- Illea	The Mark to Die the state of discourse bases			
Dispenser	Approx. 100(XL:90) pcs by weight/dispenser box.		Use ✓ Not Use Plastic under the perforation of dispenser boxes	Not use Plastic under the perforation of dispensel boxes			
Carton	10 Di	spenser boxes./ Carton.	Use ✓ Not Use Plastic bag for dispenser boxes				
Packing Me	ethod LAYER		Use ✓ Not Use Poly bag for carton Color:				
7. Loading qu	antity						
Container 2	20ft :	1392 Cartons / Container 40ft : 2838	Cartor	ns / Container 40ftHC : 3220 Cartons / Truckt : Cartons			
8. Change de	scripti	on					
For Dispen	or Dispenser box :		For Transport carton :				
STGEUVVH-	Add customer IMUNOTEHNOMED(MOLDOVA) under brand: STGEUVVH-10X100-LOFBOG-EUC-WHT-NS-BX Share artwork with brand STGEUVVH-10X100-LOFBOG-EUC-WHT-NS (NEXTECH(TURKEY) CUSTOMER)			Add customer IMUNOTEHNOMED(MOLDOVA) under brand: STGEUVVH-10X100-LOFBOG-EUC-WHT-NS-BX Share artwork with brand STGEUVVH-10X100-LOFBOG-EUC-WHT-NS-(NEXTECH(TURKEY) CUSTOMER)			
			1				







INKJET BY STGT INTERNAL DEPT.





St.B.

Reference document: SCT.QA.WI.15.002