

SRI TRANG GLOVES (THAILAND) PUBLIC COMPANY LIMITED

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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 |
|---|-----------------------------|---------------------------|

| | | | |
|---|---------------------------|--|---|
| 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 |
|---|---------------------------|--|---|

| | | | |
|---|--------------|--|---|
| 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 |
|---|--------------|--|---|


| | | | |
|--|----------------------|--|---|
| 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% |
|--|----------------------|--|---|

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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DAR-SCT-2022-0410

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 S : | | 14018224 | | | |
| Size M : | | 14018225 | | | |
| Size L : | | 14018226 | | | |
| Size XL : | | 14018227 | | | |
| 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 | - | - | - | | |
| 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: | | - | | | |

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 :

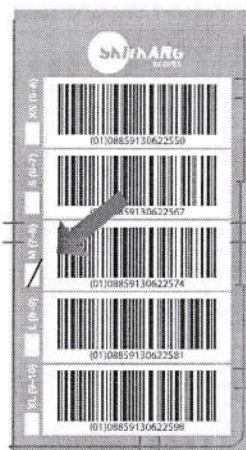
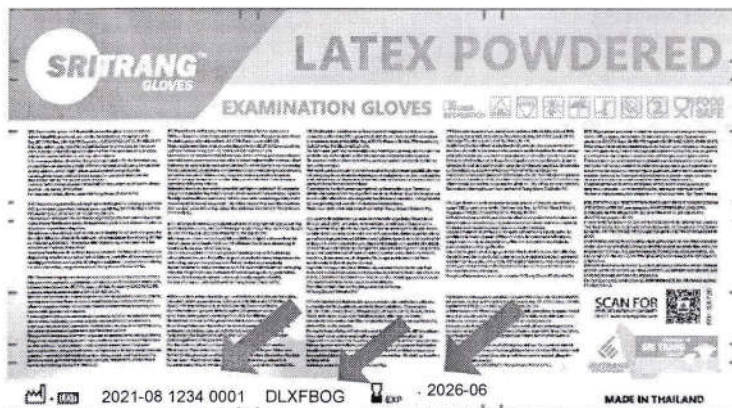
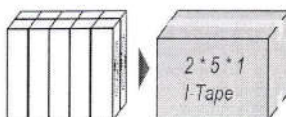
-Change format inkjet
 -Shared artwork with STGEUVRH-10X100-LXFBG-EUC-WHT-NS-BX

For Transport carton :

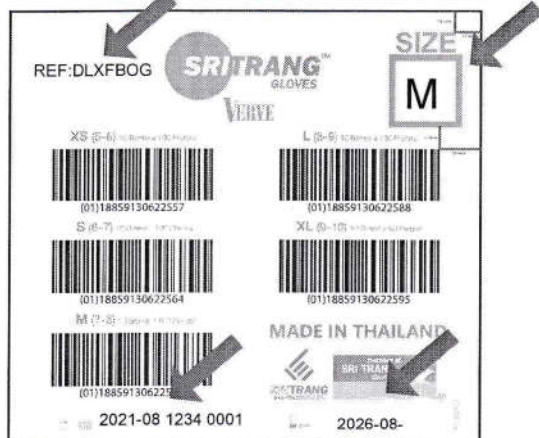
-Change format inkjet
 -Shared artwork with STGEUVRH-10X100-LXFBG-EUC-WHT-NS-BX

9. Packing format and Inkjet format

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



INKJET BY STGT INTERNAL DEPT.



St.B.