SRI TRANG GLOVES (THAILAND) PUBLIC COMPANY LIMITED

10 Soi 10 Phetkasem Rd., Hatyai, Songkhla, Thailand, 90110 Tel. (66) 074-344-663 Fax. (66) 074-344-677

SCT.PD.SP.05.483-220421 R.04 PRODUCT SPECIFICATION SHEET: NOOOGF-E-EU-M-NS DAR-SCT-2021-0558

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GLOVE SPECIFICATION

Product Specification Group Code: NOOOGF-E-EU-M-NS **Product Code: DNOFEOG (With Color)**

Product name: Nitrile 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**

Nitrije Butadiene Rubber Material:

Cuff: Rolled cuff

Surface: Textured at Finger Tip

Max. 2.0mg/glove

Thickness:

Finger: Min. 0.05mm Palm: Min. 0.05mm (single wall according to ASTM D6319, ASTM D3767)

Residual powder:

(according to EN 455-3,

EN ISO 21171)

Before Aging: Med. ≥ 6.0N Force at break: (according to EN 455-2) After Aging : Med. ≥ 6.0N

Length:

XS-XL: Med. ≥ 240mm (according to EN 455-2)

Tensile Strength: Before Aging: Min. 14Mpa (according to ASTM D6319, **ASTM D412, ASTM D573)** After Aging : Min. 14Mpa

% Elongation:

Before Aging: Min. 500% (according to ASTM D6319, After Aging : Min. 400% **ASTM D412, ASTM D573)**

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: 3 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: Medical PPE **PPE**

> EN 455 CATI CAT III **ASTM D6319** EN 420 EN 420 EN 374

EN 16523-1

1935/2004 Conformity to food regulation: 521

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 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: 4

Product Specification Code: NOOOGF-E-DOB-EU-MC-NS
Product Code: DNOFEOG DARK OCEAN BLUE

Material: Nitrile Butadiene 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*	rest-metriod
NOOOGF-E-DOB-EU-MC-NS	DARK OCEAN BLUE	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.