

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

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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
Material : Nitrile Butadiene Rubber
Cuff : Rolled cuff
Surface : Textured at Finger Tip

Thickness : (single wall according to ASTM D6319, ASTM D3767)	Finger : Min. 0.05mm	Palm : Min. 0.05mm
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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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Length : (according to EN 455-2)	XS-XL : Med. $\geq 240mm$
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Tensile Strength : (according to ASTM D6319, ASTM D412, ASTM D573)	Before Aging : Min. 14Mpa After Aging : Min. 14Mpa
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% Elongation : (according to ASTM D6319, ASTM D412, ASTM D573)	Before Aging : Min. 500% After Aging : Min. 400%
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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: 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 $30^{\circ}C$ 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 D6319</td><td>EN 420</td><td>EN 420</td></tr><tr><td></td><td></td><td>EN 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 D6319	EN 420	EN 420			EN 374			EN 16523-1
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EN 455	CAT I	CAT III														
ASTM D6319	EN 420	EN 420														
		EN 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 : NOOOGF-E-OBU-EU-MC-NS
Product Code : DNOFEOG 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*	
NOOOGF-E-OBU-EU-MC-NS	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.