

Nitrile Exam Gloves 5.0

Powder-free - Textured

X-Small, Small, Medium, Large, X-Large, XX-Large

Non-Sterile
Single Use
Ambidextrous



novaplush+™

Product Specification

Sri Trang USA, Inc.
5820 W. Cypress Street, Suite H
Tampa, FL 33607
1-888-483-6898

1. Product Information

Product Name:	Nitrile Exam Gloves 5.0					
Manufacturer Product Code:	NOF_SD Orchid					
Regulatory Status:	FDA 510(k) K193581					
Country of Origin:	Thailand					
Reorder Numbers:	X-Small	VNEG001002	Small	VNEG001003	Medium	VNEG001004
	Large	VNEG001005	X-Large	VNEG001006	XX-Large	VNEG001007

2. Design & Features

Material:	Nitrile Butadiene Rubber (NBR) This product is not made using natural rubber latex.
Intended Use:	This is a non-sterile, disposable device intended for medical purposes (except surgery) where presence of glove powder should be avoided, and is worn on the hand to prevent contamination between patient and examiner. Tested for use with chemotherapy drugs according to ASTM D6978. Chemotherapy drugs tested: 5-Fluorouracil, BleomycinSulfate, Busulfan, Carboplatin, Carmustine, Cisplatin, Cyclophosphamide (Cytoxan), Cytarabine, Dacarbazine(DTIC), Daunorubicin, Docetaxel, Doxorubicin Hydrochloride, Epirubicin, Etoposide (Toposar), Fludarabine, Gemcitabine, Idarubicin, Ifosfamide, Irinotecan, Mechlorethamine, Melphalan, Methotrexate, Mitomycin C, Mitoxantrone, Paclitaxel (Taxol), Rituximab, Thiotepe, Trisenox, Vincristine Sulfate. Contact Quality Assurance for a copy of test data. Caution: Gloves used for protection against chemotherapy drug exposure should be selected specifically for the type of chemical used. Review safety data sheets for the drug being used to determine the required level of protection. Tested for use with Fentanyl Citrate according to ASTM D6978.
Surface Treatment:	Textured
Shape:	Ambidextrous (fits either hand)
Cuff:	Rolled rim / beaded cuff
Sizes:	Extra Small (XS), Small (S), Medium (M), Large (L), Extra Large (XL), Extra Extra Large (XXL)
Color:	Orchid

3. Physical Dimensions & Properties

<u>Characteristic</u>	<u>Product Averages</u>	<u>ASTM D6319 Standard</u>
Overall Length:	244 mm (XS) 238 mm (S) 238 mm (M) 237 mm (L) 237 mm (XL) 241 mm (XXL)	220 mm minimum (XS) 220 mm minimum (S) 230 mm minimum (M) 230 mm minimum (L) 230 mm minimum (XL) 230 mm minimum (XXL)
Width:	77 mm (XS) 89 mm (S) 99 mm (M) 108 mm (L) 117 mm (XL) 133 mm (XXL)	70 ± 10 mm (XS) 80 ± 10 mm (S) 95 ± 10 mm (M) 110 ± 10 mm (L) 120 ± 10 mm (XL) 130 ± 10 mm (XL)
Thickness:	0.14 mm / 6 mils (Finger) 0.10 mm / 4 mils (Palm)	0.05 mm / 2 mils minimum (Finger) 0.05 mm / 2 mils minimum (Palm)
Tensile Strength	33 MPa (before aging) 37 MPa (after aging)	14 MPa minimum (before aging) 14 MPa minimum (after aging)
Elongation	630% (before aging) 625% (after aging)	500% minimum (before aging) 400% minimum (after aging)
Freedom from Pinholes	AQL ≤ 1.5 Note: Sri Trang USA, Inc. utilizes a more stringent specification than ASTM (AQL ≤ 2.5)	

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4. Quality Assurance & Quality Control

Performance requirements for quality characteristics are in accordance with ISO 2859-1, Sampling Procedures for Inspection by Attribute. Sampling for inspection in accordance with ISO 2859 (unit 1 glove).

Barrier Defects (Inspection Level GI, AQL ≤ 1.5) – Holes that result in the malfunction of the glove as a protective barrier and may affect the physical appearance

Major Visual Defects (Inspection Level GI, AQL ≤ 1.5) – Defects that disrupt the glove's function for its intended use or that may cause undesirable user experience

Minor Defects (Inspection Level GI, AQL ≤ 4.0) – Aggregated visual defects for are non-conformities of lower degree of concern, which do not prevent correct use of gloves. Minor cosmetic defects which do not affect performance.

The gloves are manufactured using Good Manufacturing Practices (cGMP) and the manufacturer is compliant with ISO 9001:2015, ISO 13485:2016, and US FDA QSR listed in 21 CFR Part 820.

5. Packaging

Marking:	Packaging marked with designated size (gloves not marked)		
Packaging:	Standard packaging is 200 pieces per box / 180 pieces per box XL, XXL (by weight), 10 boxes per case Other packaging may be available upon request.		
Packaging Dimensions:	Inner Box (dispenser)		Case
	Width	128 mm / 5.04"	255 mm / 10.04"
	Length	245 mm / 9.65"	418 mm / 16.46"
	Height	80 mm / 3.15"	264 mm / 10.39"

6. Storage & Handling

Keep storage 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, such as sunlight, and oxidizing agents.

Storage above 86°F (30 °C) will lead to accelerated aging and should be avoided. Long term storage in bulk can lead to pleats, stickiness, and early aging of the glove and should be avoided.

Shelf Life – Product has a 3 year shelf-life from manufacture date.

7. Contact & Reporting Information

<u>Department</u>	<u>Number</u>	<u>Email</u>
Customer Service	1.888.483.6898	customer.service@sritrangusa.com
Quality Assurance	1.888.483.6898 (813) 606.4301	customer.service@sritrangusa.com