

PRODUCT SPECIFICATION

Nephron Nitrile, LLC
4777 12th Street Extension | West Columbia, SC 29172-3033



1. PRODUCT INFORMATION

Product Name: **Black Cherry Nitrile Powder-Free Examination Polymer Coated Chemo & Fentanyl Tested Fingertip Textured Black**

Order Numbers: 200201001 (XS) 200204004 (L)
200202002 (S) 200205005 (XL)
200203003 (M) 200206006 (XXL)

Regulatory Status: FDA 510k cleared

Country of Origin: United States of America

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 where presence of glove powder should be avoided and is worn on the hand. Tested for use with gastric acid, chemotherapeutics and fentanyl. Chemotherapy drugs tested: Doxorubicin Hydrochloride, Cyclophosphamide (Cytoxan), Paclitaxel (Taxol), Etoposide (Toposar), 5 - Fluorouracil (5-Flu), Cytarabine HCl (Cytosine), Fludarabine, Gemcitabine, Irinotecan, Methotrexate (Amethopterin), Bleomycin Sulfate, Busulfan, Carboplatin, Cisplatin, Dacarbazine, Daunorubicin HCl, Docetaxel (Taxotere), Epirubicin (Ellence), Idarubicin, Ifosfamide, Mechlorethamine HCl, Melphalan, Mitomycin, Mitoxantrone, Rituximab, Trisonex (Arsenic Trioxide), Vincristine Sulfate (Oncovin)

Surface Treatment: Textured

Shape: Ambidextrous (fits either hand)

Cuff: Rolled / beaded cuff

Sizes: Extra Small (XS), Small (S), Medium (M), Large (L), Extra Large (XL), Extra Extra Large (XXL)

Color: Black

3. PHYSICAL DIMENSIONS & PROPERTIES

OVERALL LENGTH:				
SIZE	NUMERICAL	PRODUCT AVERAGES	ASTM D6319 STANDARD	TOLERANCE
X-Small	5-6	240 mm	220 mm minimum	+/- 5 mm
Small	6-7	240 mm	220 mm minimum	+/- 5 mm
Medium	7-8	240 mm	230 mm minimum	+/- 5 mm
Large	8-9	240 mm	230 mm minimum	+/- 5 mm
X-Large	9-10	240 mm	230 mm minimum	+/- 5 mm
XX-Large	10-11	240 mm	230 mm minimum	+/- 5 mm
WIDTH				
SIZE	NUMERICAL	PRODUCT AVERAGES	ASTM D6319 STANDARD	TOLERANCE
X-Small	5-6	70 mm	70 ± 10 mm	+/- 10 mm
Small	6-7	85 mm	80 ± 10 mm	+/- 10 mm
Medium	7-8	95 mm	95 ± 10 mm	+/- 10 mm
Large	8-9	110 mm	110 ± 10 mm	+/- 10 mm
X-Large	9-10	120 mm	120 ± 10 mm	+/- 10 mm
XX-Large	10-11	130 mm	130 ± 10 mm	+/- 10 mm
Fingertip Thickness Single Wall:		0.114 mm (4.5 mil)	0.05 mm/2 mil minimum	+/-0.0001 mm (0.5 mil)
Palm Thickness Single Wall:		0.101 mm (4.0 mil)	0.05 mm/2 mil minimum	+/-0.001 mm (0.5 mil)

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TENSILE STRENGTH	> 20 mPa (before aging)	14 MPa minimum (before aging)
	> 20 mPa (after aging)	14 MPa minimum (after aging)
ELONGATION	> 500% (before aging)	500% minimum (before aging)
	> 400% (after aging)	400% minimum (after aging)
FREEDOM FROM PINHOLES	AQL ≤ 2.5	

4. QUALITY ASSURANCE & QUALITY CONTROL

Performance requirements for quality characteristics are sampled 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 ≤ 2.5) – 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 ≤ 4.0) – Defects that disrupt the glove's function for its intended use or that may cause undesirable user experience.

The gloves are manufactured using Good Manufacturing Practices (cGMP) in accordance with 21 CFR Part 820 and the product adheres to ASTM D6319-19.

5. PACKAGING

Marking: Packaging marked with designated size (gloves not marked)

Packaging: 100 pieces per box / 90 pieces per box XXL, 10 boxes per case

Packaging Control #: Each packaging unit (dispenser box) and outer case carry a control number

SIZE	DISPENSER BARCODE (UPC-A)	DISPENSER WEIGHT	CASE WEIGHT
XS	TBD	1.04 lbs.	12.20 lbs.
S	TBD	1.10 lbs.	12.80 lbs.
M	TBD	1.16 lbs.	13.40 lbs.
L	TBD	1.21 lbs.	13.90 lbs.
XL	TBD	1.28 lbs.	14.60 lbs.
XXL	TBD	1.34 lbs.	15.20 lbs.

PACKAGING	DISPENSER	CASE
Width	4.94"	9.88"
Length	9.69"	15.31"
Height	2.87"	10.13"

6. STORAGE & HANDLING

Nephron Nitrile recommends that Medical Exam Black gloves (all sizes) are to be stored in their original, unopened packaging. Store in cool, dry conditions. Avoid direct sunlight, fluorescent lighting or other ozone sources. Do not store above 38 °C (100°F). After delivery, improper storage or handling of the product can adversely affect product quality. Nephron Nitrile will not be held liable for any resulting damage when stored improperly.

7. CONTACT & REPORTING INFORMATION

DEPARTMENT	NUMBER	EMAIL
Customer Service	1.844.937.3888	nitrilesales@nephronnitrile.com