

iSense® Blue Nitrile Powder-Free Disposable Gloves

Brand Name: iSense® Non-Sterile Powder-Free Nitrile Examination Disposable Gloves

Intended Use:

To conduct medical examination, diagnostic and therapeutic procedures to protect patient and user from cross contamination or infection.

Materials

Nitrile (Carboxylated Butadiene Acrylonitrile).

Type: Nitrile Examination Glove, powder free, online single chlorinated, non-sterile, ambidextrous, single-use only.

Color: Blue

UOM: 100 gloves

Surface Finish: Fully textured, beaded cuff.

Shelf Life: A shelf life of five years from the date of manufacture with the correct storage conditions.

Storage Condition: Gloves shall maintain their properties when stored in a dry condition. Avoid direct sunlight.

Dimensions	Size	Palm width	Length (inches)
Inches (Millimetres)	Small	4.45" ± 0.1" (84 ± 3mm)	9" (240mm min)
	Medium	3.70" ± 0.1" (94 ± 3mm)	9" (240mm min)
	Large	4.13" ± 0.1" (105 ± 3mm)	9" (240mm min)
	Extra Large	4.45" ± 0.1" (113 ± 3mm)	9" (240mm min)

Thickness

Single wall thickness 5.5 mils

Quality Specification

* AND – Accept No Defects
Water Tight Test G1 – AQL 1.5
Residual Powder n = 5 (average)

Residual Powder

Maximum 10mg/dm²

Physical Properties	Un-Aged	Aged
Force of Break (N)	6 Min	6 Min



Glove Standard



Standards

ASTM D 6978 Fentanyl Permeation
HACCP International Food Safe Certified
FDA 21 CFR 177.26000 (e) & (f)
iSense® meets ATSM D6319 for Medical Exam use
ASTM D 6978 Chemo Compliant - Breakthrough times on page 2
EN374-3:2016
EN374-2:2016
- Air Leaks Pass
- Water leak test Pass

Packaging Configuration & Labeling

Packaging 100 gloves per inner box
(by weight) 10 boxes per outer carton.
Box dimension 8.86"(L) x 4.72"(W) x 2.36"(D)
Barcodes GS1 format

Part No.

Small	230 001
Medium	230 002
Large	230 003
Extra Large	230 004



ASTM D 6978 Permeation Test Results on: Non-Sterile Powder-Free Nitrile Exam Gloves Blue

TEST CHEMOTHERAPY DRUG & CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen 1/2/3) (Minutes)	AVERAGE STEADY STATE PERM. RATE (Specimen 1/2/3) ($\mu\text{g}/\text{cm}^2/\text{minute}$)	OTHER OBSERVATIONS
Carboplatin 10.0mg/ml (10,000ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Carmustine (BCNU), 3.3 mg/ml (3,300ppm)	1.84 (2.04, 3.44, 1.84)	0.7 (0.5, 1.5, 0.2)	Moderate swelling and no degradation
Cisplatin 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Dacarbazine (DTIC), 10.0 mg/ml (10,000ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and degradation
Fluorouracil, 50.0 mg/ml (50,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Ifosfamide, 50.0 mg/ml (50,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Methotrexate, 25.0 mg/ml, (25,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Mitomycin C, 0.5 mg/ml (500 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Mitoxantrone, 2.0 mg/ml (2,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	No breakthrough up to 240 min.	N/A	Moderate swelling and no degradation
Thiotepa, 10.0 mg/ml (10,000 ppm)	0.76 (2.13, 0.76, 4.48)	05 (0.2, 0.7, 0.7)	Slight swelling and no degradation
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation

TEST DRUG & CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen 1/2/3) (Minutes)	AVERAGE STEADY STATE PERM. RATE (Specimen 1/2/3) ($\mu\text{g}/\text{cm}^2/\text{minute}$)	OTHER OBSERVATIONS
Fentanyl Citrate Injection, 100.0 mcg/2ml	No breakthrough up to 240 min.	N/A	Slight swelling; no degradation