

TECHNICAL DATA SHEET



FEATURES & BENEFITS

- These nitrile gloves offer superior puncture, tear and chemical resistance without compromising dexterity or tactility.
- Textured fingertips ensure a secure grip, even when wet.
- Chemo tested.

RECOMMENDED USE

- Non-sterile, single use, medical examination gloves are intended to prevent transmission of a wide variety of diseases to both patients and health care personnel. Specifically, gloves are intended to act as a barrier between the healthcare provider and patients to prevent contamination between patient and caregiver.

CERTIFICATION & STANDARDS

ISO 13485 certified manufacturer.
Class 2 Medical Device.
Health Canada registered medical device manufacturer.

STORAGE CONDITIONS

These gloves should be disposed of after each use.
Store in a cool, dry place.
Avoid excessive heat (40 °C or 104 °F).
Recommended storage temperature: 10-30 °C.
Shield open box from direct sun and fluorescent light.
Shelf Life: 3 years.

PRODUCT DETAILS

Product Name:	Medicom AssureTouch® Agile Nitrile Powder-Free Medical Examination Gloves
Product Type:	Single-use, non-sterile, ambidextrous
Material:	Nitrile
Colour:	Blue
Quantity per Box:	100
Specs:	4.5 mils, 6.2 g
Country of Origin:	Malaysia

GLOVE SPECIFICATIONS					
CHARACTERISTIC			TEST METHODS	ACCEPTABLE LIMIT	
Dimension & Tolerance	Width (mm)		ASTM D 3767	Extra-Small (XS)	60 - 85
				Small (S)	70 - 90
				Unisize	75 - 95
				Medium (M)	85 - 105
				Large (L)	101 - 121
				Extra-Large (XL)	110 - 130
				XX-Large (XXL)	120 - 140
	Length (mm)			XS & S: ≥ 220 Others: ≥ 230	
	Thickness (mm)	Palm		≥ 0,05	
Finger					
Water Tightness Test (Freedom from Holes)			ASTM D 5151	As prescribed by Inspection Level and AQL	
Physical Requirement	Before Ageing	Tensile Strength	ASTM D 412	≥ 14 MPa	
		Ultimate Elongation		≥ 500%	
	After Ageing	Tensile Strength		≥ 14 MPa	
		Ultimate Elongation		≥ 400%	
Powder Residue	Powder Free Gloves		ASTM D 6124	≤ 2,0 mg/glove, Inspection Level N=5	
	Powdered Gloves			≤ 10,0 mg/dm2, Inspection Level N=2	



CHEMOTHERAPY CHART	
CHEMOTHERAPY DRUG AND CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME
Carboplatin / Carboplatine, 10,0 mg/ml	>240 minutes
Carmustine, 3,3 mg/ml	11.3 minutes
Cisplatin (BCNU), 1,0 mg/ml	>240 minutes
Cyclophosphamide (Cytoxan), 20,0 mg/ml	>240 minutes
Dacarbazine (DTIC), 10,0 mg/ml	>240 minutes
Doxorubicin Hydrochloride / Chlorhydrate de doxorubicine, 2,0 mg/ml	>240 minutes
Etoposide (Toposar) / Étoposide (Toposar), 20,0 mg/ml	>240 minutes
Fluorouracil / Fluorouracile, 50,0 mg/ml	>240 minutes
Ifosfamide, 50,0 mg/ml	>240 minutes
Methotrexate / Méthotrexate, 25,0 mg/ml	>240 minutes
Mitomycin C / Mitomycine C, 0,5 mg/ml	>240 minutes
Mitoxantrone, 2,0 mg/ml	>240 minutes
Paclitaxel (Taxol), 6,0 mg/ml	>240 minutes
Thiotepa / Thiotépa, 10,0 mg/ml	7.4 minutes
Vincristine Sulfate / Sulfate de vincristine, 1,0 mg/ml	>240 minutes

*The aforementioned chemicals have been tested with these gloves.

WARNING: DO NOT USE WITH CARMUSTINE AND THIOTEPA.

CAUTION: Testing showed an average breakthrough time of 11.3 minutes with Carmustine and 7.4 minutes with Thiotepa 10.0 mg/ml.

Gloves used for protection against chemotherapy drug exposure should be selected specifically for the type(s) of chemicals used. Users should review drug labeling or material safety data sheets for the drugs being used to determine an adequate level of protection.

The gloves have been tested according to ASTM D6978. Tested for use with chemotherapy drugs.

Store in a cool dry place. Avoid excessive heat (40 °C/104 °F). Shield open box from direct sun and fluorescent lighting.

Appendix 1 (List of items)

Item Code	Description	Packaging Information	Size	Color	Specific Attribute	Treatment	Marketed in USA as	Marketed in Canada as
9998	Medicom AssureTouch Agile Powder-Free Nitrile Medical Examination Gloves	100 Gloves/Box, 10 Boxes/Case, 1000 Gloves/Case Gloves are in a cardboard. Case made with suitable corrugated fiberboard to withstand transportation and storage	A = X-small, B = Small, C = Medium, D = Large, E = X-Large	Blue	Country of origin: Malaysia	Non-Sterile	Medical Device Class 1	Medical Device Class 2

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