

## TECHNICAL DATA SHEET

### FEATURES & BENEFITS

- The unrivaled strength of nitrile delivers enhanced barrier protection and exceptional fit, while providing the tactile sensitivity necessary for the most complex procedures.
- Designed to fit like a glove should, while providing the tactile sensitivity needed for the most complex procedures.
- Textured fingertips for a secure grip, even when wet.

### 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:	<b>Medicom SafeBasics® True Fit Thin™ Powder-Free Nitrile Medical Examination Gloves</b>
Product Type:	Single-use, non-sterile, ambidextrous
Material:	Nitrile
Colour:	Blue or Pink
Quantity per Box:	300
Specs:	3 mil, 3.5 g (Blue), 2.5 mil, 3.2 g (Pink)
Country of Origin:	Malaysia

### GLOVE SPECIFICATIONS

CHARACTERISTIC		ACCEPTABLE LIMIT	
Dimension & Tolerance	Width (mm)	Extra-Small (XS)	60 - 80
		Small (S)	70 - 90
		Unisize (S-M)	75 - 95
		Medium (M)	85 - 105
		Large (L)	100 - 120
		Extra-Large (XL)	110 - 130
		XX-Large (XXL)	120 - 140
	Length (mm)	XS & S ≥ 220 Others: ≥ 230	
Thickness (mm)	Palm	≥ 0,05	
	Finger		
Physical Requirement	Before Ageing	Tensile Strength	≥ 14 MPa
		Ultimate Elongation	≥ 500%
	After Ageing	Tensile Strength	≥ 14 MPa
		Ultimate Elongation	≥ 400%
Powder Residue	Powder Free Gloves	≤ 2,0 mg/glove	
	Powdered Gloves	≤ 10,0 mg/dm <sup>2</sup>	



### CHEMOTHERAPY CHART [1185 - BLUE]

CHEMOTHERAPY DRUG AND CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME
Carmustine, 3,3 mg/ml	23.3 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
Methotrexate / Méthotrexate, 25,0 mg/ml	>240 minutes
Mitomycin C / Mitomycine C, 0,5 mg/ml	>240 minutes
Paclitaxel (Taxol), 6,0 mg/ml	>240 minutes
Thiotepa / Thiotépa, 10,0 mg/ml	58.2 minutes
Vincristine Sulfate / Sulfate de vincristine, 1,0 mg/ml	>240 minutes
Fentanyl and Concentration Fentanyl Citrate Injection	>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 23.3 minutes with Carmustine and 58.2 minutes with Thiotepa 10.0 mg/ml.

### CHEMOTHERAPY CHART [1186 - PINK]

CHEMOTHERAPY DRUG AND CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME
Carmustine, 3,3 mg/ml	22.2 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
Methotrexate / Méthotrexate, 25,0 mg/ml	>240 minutes
Mitomycin C / Mitomycine C, 0,5 mg/ml	>240 minutes
Paclitaxel (Taxol), 6,0 mg/ml	>240 minutes
Thiotepa / Thiotépa, 10,0 mg/ml	37.3 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 22.2 minutes with Carmustine and 37.3 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	Treatment	Marketed in USA as	Marketed in Canada as
1185	Medicom SafeBasics "True Fit Thin" Powder-Free Nitrile Medical Examination Gloves	300 Gloves/Box, 8 Boxes/Case, 2400 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	Non-Sterile	Medical Device Class 1	Medical Device Class 2
1186	Medicom SafeBasics "True Fit Thin" Powder-Free Nitrile Medical Examination Gloves	300 Gloves/Box, 8 Boxes/Case, 2400 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	Pink	Non-Sterile	Medical Device Class 1	Medical Device Class 2

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