



# Cubed3

## Nitrile Medical Examination Gloves Powder Free

### Chemotherapy Nitrile Examination Powder Free Glove

An excellent option for chemotherapy applications where a high level of protection is needed. Available with option for use with 32 Chemotherapy Drugs and Fentanyl. Nitrile Glove is the most popular and reliable glove for medical healthcare and dental industries. Made of premium compounded nitrile eliminating latex allergy concern. It comes with excellent fit, comfort, sensitivity and protection. Its textured surface helps to provide secure grip and added handling precision. Proudly available in an extensive selection of colours giving businesses more options.

### Standards And Certifications

- Conforms to ASTM D6319 and EN455 (1 - 4) Standards
- Manufactured under QSR(GMP), ISO9001 : 2015 and ISO13485 : 2016 QMS
- Biocompatibility tested under ISO 10993
- Conforms to MDD 93/42/EEC Class I

Tested For Use With Chemotherapy Drugs

In accordance with ASTM D6978-05 and US FDA 510K ( Medical Device )



## PRODUCT SPECIFICATION (Cubed3NM35-Chemo)

### Nitrile Powder Free Examination Gloves Finger Textured - Chemo

#### SECTION I : PRODUCT DESCRIPTION

Type	Nitrile Examination Glove, Powder Free, Online Single Chlorinated, Non sterile
Material	100% Synthetic Nitrile Latex
Colour	Blue
Design and Feature	Ambidextrous, finger textured, beaded cuff
Powder	No powder lubricant added
Storage Condition	The gloves shall maintain their properties when stored in a dry condition. Avoid direct sunlight.
Shelf Life	The gloves shall have shelf life of 5 years from the date of manufacture with the above storage condition.
Packing Style	100 pcs gloves x 10 dispensers x 1 carton
Size Marking	The size of gloves shall be marked in the check box on every carton with black ink.
Application	Medical, HealthCare, Dental. Tested for use with chemotherapy drugs.

#### SECTION II: PERFORMANCE REQUIREMENTS

##### Sampling Plan : ISO 2859 Single Normal

#	Characteristics	Inspection Level	Acceptable Quality Level	Reference Standard
1	Dimensions	S2	4.0	ASTM D6319-19
2	Physical Properties	S2	4.0	ASTM D6319-19
3	Freedom from Holes Water Tight Test	GI	1.5	ASTM D6319-19 ASTM D5151-19
4	Visual Defects: I Major Visual ii Minor Visual	GI	2.5 4.0	In house practice
5	Chemotherapy Drugs Testing	N/A		ASTM D6978-05 (2019)
6	Packaging Defects: I Regulatory II Visual III Critical incl. Gloves Counting	GI GI S2	** 4.0 4.0	In house practice
7	Powder Free Residue	N=5	N/A	ASTM D6319-19 ASTM D6124-06 (2017)
8	Mix Size/ Mix Gloves/ Mix hand	Not Allowed		

## SECTION III: PERFORMANCE SPECIFICATION

### 3.1 Dimensions

Description	Size	Standard
Length, mm	All Sizes	Min 240
Palm Width, mm	XS	76+/-3
	S	84+/-3
	M	94+/-3
	L	105+/-3
	XL	113+/-3
Thickness, mm *single wall	All Sizes	Finger: 0.09+/-0.02 Typical value: 0.09 to 0.11 Palm: 0.07+/-0.02 Typical value: 0.06 to 0.07

### 3.2 Physical Properties

Description	Standard	
	Before Aging	After Aging
Elongation at Break, %	Min 500 Typical value: 500 to 600	Min 400 Typical value: 400 to 500
Tensile Strength, MPa	Min 14 Typical value: 14 to 18	Min 14 Typical value: 14 to 18

### 3.3 Chemotherapy Drugs Tested

#	Drugs	Min. Breakthrough Time, Minutes
1	Carmustine, BCNU	10.1
2	Cisplatin	>240
3	Cyclophosphamide, Cytosan	>240
4	Dacarbazine, DTIC	>240
5	Doxorubicin Hydrochloride	>240
6	Etoposide, Toposar	>240
7	Fluorouracil	>240
8	Paclitaxel, Taxol	>240
9	Thiotepa	20.2
10	Amethopterin Hydrate	>240
11	Methotrexate	>240
12	Mitomycin C	>240
13	Vincristine Sulfate	>240

\*Warning: Do not use with Carmustine, BCNU and Thiotepa

### 3.4 Biocompatibility Tested

Biocompatibility Test Results on Nitrile Blue Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs. Reference Standard: ISO 10993-10:2010.

Biocompatibility Test	Test Results
Primary Skin Irritation	PASSES Not a primary skin irritant under condition of the study
Skin Sensitization	PASSES Not a contact sensitizer under condition of the study

### 3.5 Freedom from Holes

The sample size and allowable number of non conforming gloves in the samples shall be determined in accordance to Sampling Plan ISO 2859-1 Single Normal using inspection and acceptable quality level as stated in Section II: Performance Requirements.

### 3.6 Visual Defects

The sample size and allowable number of non conforming gloves in the samples for both major and minor defects shall be determined in accordance to Sampling Plan ISO 2859-1 Single Normal using inspection and acceptable quality level as stated in Section II: Performance Requirements.

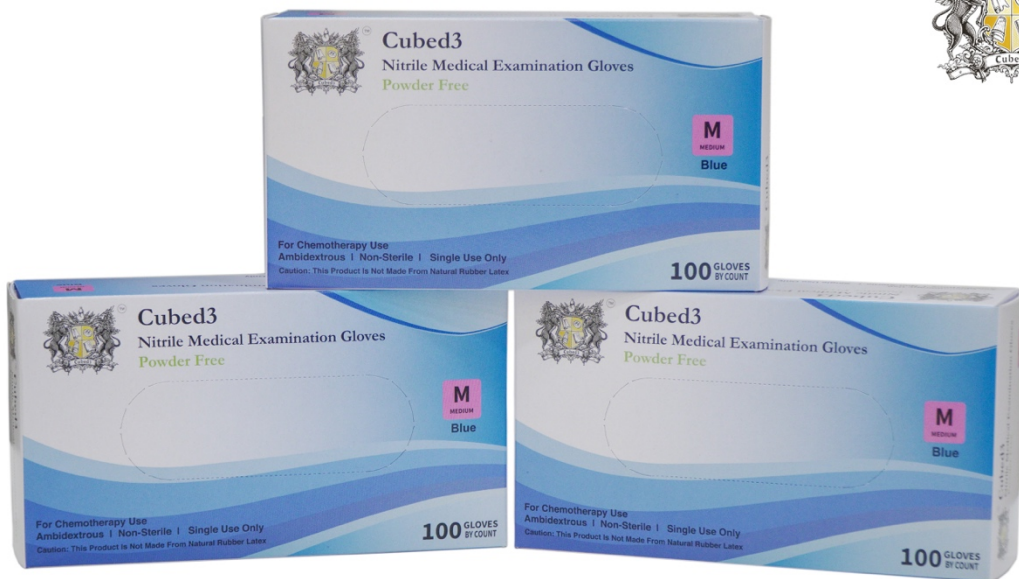
### 3.7 Packaging Defects

The Sample size and allowable number of non conforming in the samples for regulatory, visual and critical packaging defects shall be determined in accordance to Sampling Plan ISO 2859-1 Single Normal using inspection and acceptable quality level as stated in Section II: Performance Requirements, Gloves Counting=100 pcs by count per Dispenser.

### 3.8 Powder Free Residue

Maximum 2 mg per glove

#### Cubed3 NM35USA-Chemo



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