Core Nitrile Examination Powder Free Glove

Technical Data Sheet (Regular and Long Cuff)

Core Nitrile Examination Glove is used as a good biological & chemical barrier to protect the user's hands against contamination and dangerous substances. It 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.

1. Product Specification

Material:	Synthetic Nitrile Latex
Type:	Powder free, non-sterile
Color:	Blue
Design and Features:	Finger textured (regular cuff) or Palm textured (long cuff) surface, Ambidextrous, Beaded cuff, Online single chlorinated or Polymer coated, Excellent chemical, and puncture resistance. Tested for use with chemotherapy drugs.
Size:	XS, S, M, L, and XL
Weight:	Regular Cuff (3.5gm), Long Cuff (6.2gm) Size M (+/- 0.2)
Storage:	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.
Application:	Medical, Healthcare, Dental
Packing Style:	100 gloves x 10 dispensers x 1 carton
AQL	1.5

2. Quality Performance

Quality Standards

- Manufactured under QSR (GMP), ISO 9001:2015 and ISO 13485:2016 Quality Management System
- Medical Device Regulation (MDR) Declaration of Conformity

- Conforms to ASTM D6319, ASTM D5151-19, ISO 11193 Standards
- Complies to PPE Regulation (EU) 2016/425 requirements.
- EN 455 – 1,2,3,4, Declaration of Conformity PPE Category III, EN 374 – 1,2,4,5, Module B Module C2/D ASTM D 6319, ASTM / FDA 510(k) Variant Available

Functional Benefits

- A good barrier protection against contamination and dangerous substances. Tested for use with chemotherapy drugs.
- An alternative solution for individuals who are allergic to Natural Rubber Latex.
- Free from latex protein, eliminating Type I Immediate Hypersensitivity reaction.
- Custom design enhanced comfort and fit.
- Finger or palm textured enhanced wet and dry grip with added handling precision.
- Chlorinated or polymer powder free interior promote smooth donning & doffing experience.

3. Physical Dimension & Physical Properties

Physical

Dimension Regular

Cuff

Size	Length (mm)	Palm width (mm)	Thickness: Single wall	Reference Standard
XS	Min 240	76 ± 3	Finger: 0.08 to 0.11 mm (3.1 to 4.3 mil) Palm: 0.06 to 0.07 mm (2.4 to 2.8 mil)	ISO 11193-1:2020
S		84 ± 3		
M		94 ± 3		
L		105 ± 3		
XL		113 ± 3		

Long Cuff

Size	Length (mm)	Palm width (mm)	Thickness: Single wall	Reference Standard
XS	300 ± 10	76 ± 3	Finger: 0.13 to 0.15 mm (5.1 to 5.9 mil) Palm: 0.10 to 0.11 mm (3.9 to 4.3 mil)	ISO 11193-1:2020
S		84 ± 3		
M		94 ± 3		
L		105 ± 3		
XL		113 ± 3		

Physical Properties

Description	Before Aging	After Aging	Reference Standard
Elongation at Break, %	Min 500 Typical value: 500 to 600	Min 400 Typical value: 500 to 600	ISO 11193-1:2020
Force at Break, N	Min 7 Typical value: 9 to 12	Min 6 Typical value: 10 to 13	

4. Product Safety Conformance

CHEMICAL RESIDUE TESTED **PASS**

Purpose: To ensure the gloves are free from any chemical substances and safe to use.

Chemical Test (s)	Test Results (µg/g)
Butylated Hydroxyanisole (BHA)	Not Detected
Butylated Hydroxytoluene (BHT)	Not Detected
Diphenyl Guanidine (DPG)	Not Detected
Diphenyl Thiourea (DPT)	Not Detected
Mercaptobenzothiazole (MBT)	Not Detected
Tetramethylthiuram Disulphide (TMTD)	Not Detected
Zinc Dibutyldithiocarbamate (ZDBC)	Not Detected
Zinc Diethyldithiocarbamate (ZDEC)	Not Detected
Zinc Dimethyldithiocarbamate (ZDMC)	Not Detected
Zinc Mercaptobenzimidazole (ZMBI)	Not Detected
Zinc Mercaptobenzothiazole (ZMBT)	Not Detected
Zinc Pentamethyleneditithiocarbamate (ZPMC)	Not Detected

PASS

PHTHALATES TESTED

Purpose: To ensure the gloves are free from any chemical substances and safe to use.

Chemical Test (s)	Test Results (µg/g)
Dibutyl Phthalate (DBP)	Not Detected
Di(2-ethylhexyl) Phthalate (DEHP)	Not Detected
Di-n-octyl Phthalate (DNOP)	Not Detected
Di-isononyl Phthalate (DINP)	Not Detected
Di-isodecyl Phthalate (DIDP)	Not Detected

Benzyl butyl Phthalate (BBP)	Not Detected

HEAVY METAL TESTED PASS

Reference: EPA Method 3052	
Purpose: To ensure the gloves are free from heavy metal substances and safe to use.	
Chemical Test (s)	**Test Results (µg/g)**
Cadmium (Cd)	Not Detected
Lead (Pb)	Not Detected
Mercury (Hg)	Not Detected
Arsenic (As)	Not Detected
Antimony (Sb)	Not Detected
Tin (Sm)	Not Detected

BIOCOMPATIBILITY TESTED PASS

Reference: ISO 10993-10 (Test for Skin Irritation and Skin Sensitization)	
Purpose: Biological evaluation for medical devices for irritation and delayed type hypersensitivity.	
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

CHEMOTHERAPY DRUGS TESTED PASS

Reference: ASTM D6978-05 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs	
Purpose: Gloves are tested for permeability to specific chemotherapy drugs	
Test Chemotherapy Drug and Concentration	**Minimum Breakthrough Detection Time (minutes)**
Amethopterin 25.0 mg/ml (25,000 ppm)	No breakthrough up to 240 min
Bleomycin Sulfate 15.0 mg/ml (15,000 ppm)	No breakthrough up to 240 min
Bursulfan 6.0 mg/ml (6,000 ppm)	No breakthrough up to 240 min
Carboplatin 10.0 mg/ml (10,000 ppm)	No breakthrough up to 240 min
Carmustine (BCNU) 3.3 mg/ml (3,300 ppm)	**11 Not recommended to use**
Cisplatin 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240 min

Cyclophosphamide (Cytoxan) 20.0 mg/ml (20,000 ppm)	No breakthrough up to 240 min
Dacarbazine (DTIC) 10.0 mg/ml (10,000 ppm)	No breakthrough up to 240 min
Docetaxel 10.0 mg/ml (10,000 ppm)	No breakthrough up to 240 min
Doxorubicin Hydrochloride 2.0 mg/ml (2,000 ppm)	No breakthrough up to 240 min
Ellsnce 2.0 mg/ml (2,000 ppm)	No breakthrough up to 240 min
Etoposide (Toposar) 20.0 mg/ml (20,000 ppm)	No breakthrough up to 240 min
Fludarabine 25.0 mg/ml (25,000 ppm)	No breakthrough up to 240 min
Fluorouracil 50.0 mg/ml (50,000 ppm)	No breakthrough up to 240 min
Gemcitabine 38.0 mg/ml (38,000 ppm)	No breakthrough up to 240 min
Idarubin 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240 min
Ifosfamide 50.0 mg/ml (50,000 ppm)	No breakthrough up to 240 min
Irinotecan 20.0 mg/ml (20,000 ppm)	No breakthrough up to 240 min
Mechlorethamine 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240 min
Melphalan 5.0 mg/ml (5,000 ppm)	No breakthrough up to 240 min
Methotrexate, 25.0 mg/ml (25,000 ppm)	No breakthrough up to 240 min
Mitomycin C 0.5 mg/ml (500 ppm)	No breakthrough up to 240 min
Mitoxantrone 2.0 mg/ml (2,000 ppm)	No breakthrough up to 240 min
Oxaliplatin 5.0 mg/ml (5,000 ppm)	No breakthrough up to 240 min
Paclitaxel (Taxol) 6.0 mg/ml (6,000 ppm)	No breakthrough up to 240 min
Rituximab 10.0 mg/ml (10,000 ppm)	No breakthrough up to 240 min
Thiotepa 10.0 mg/ml (10,000 ppm)	**39 Not recommended to use**
Topotecan 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240 min
Trisenox 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240 min
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240 min
Vinorelbine 10.0 mg/ml (10,000 ppm)	No breakthrough up to 240 min
Fentanyl Citrate Injection 100 mcg/2ml	No breakthrough up to 240 min

VIRAL PENETRATION TESTED **PASS**

Reference: ASTM F1671- 13 “Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phl-X 174 Bacteriophage Penetration as a Test System”	
Purpose: To test the barrier protection of the gloves from the passages of the viruses.	
Viral Penetration	**Test Results**
	PASSES

5. Others

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.

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.

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.

Powder Free Residue

Maximum 2 mg per glove *(Reference Standard: ASTM D6319-19, ASTM D6124-06 (2017))*
Carmusitine and thiotepa have extremely low permeation times of 11 minutes and 39 minutes respectively.