Cobalt Blue 3.5g
Nitrile Powder Free Examination Glove

Nitrile Powder Free Examination Glove (ASTM & EN)

Product Specification

Product Code	N035CBB-OC-24FT
Product Type	Non-Sterile, Powder-Free, Nitrile, Ambidextrous, Examination Glove
Color	Cobalt Blue
Intended Use	Medical use - for medical examinations and procedures to help prevent contamination between healthcare workers and patients.
Product Conformance	This product meets the current version of ASTM D6319, EN 455-1,2,3 and 4, and Customer Requirements / Category I - PPE (EU 2016/425) / EN ISO 21420:2020 / Food Contact : UNI EN1186, EN13130. This product is also manufactured in accordance with a quality management system that conforms to ISO 9001 and ISO 13485.
Material	Nitrile Butadiene Rubber
Cuff Finishing	Beaded
Surface Finishing	Finger Textured
Other Requirements	Other requirements, including labelling and packaging, is subject to customer and market regulatory requirements and is specified in the Customer Product Sheet.
Certificate of Release	A Certificate of Release is available upon request to ensure all products confirm to specification.

Requirement: PAH content per EN ISO 21420:2020	< 0.2 mg/kg (of each PAH listed in the appendices)	Pass
Requirement: REACH 1907/2006 annex XVII entry number 50	< 0.01% (w/w) of each SVHC Candidate List	Pass

Physical Dimension

Size	XS	S	M	L	XL
Palm Width (mm)	75 ± 5	85 ± 5	95 ± 5	105 ± 5	115 ± 5
Length (mm) (min.)	240 mm				
Weight (g)	3.5±0.3g				
Location of Thickness Measurement	Single Wall (mm)				
~ Cuff (25 ± 5 mm from cuff edge)	≥ 0.05				
~ Palm (33 ± 5 mm from crotch)	≥ 0.05				
~ Finger (13 ± 3 mm from fingertip)	≥ 0.07				

Physical Properties

Criteria	Before Aging	After Aging
Tensile Strength (Mpa) (min.)	14	14
Elongation (%) (min.)	500	400
Force at Break (N) (Median)	6	6

Pre-shipment Inspection

Characteristic	Dimension	Physical Properties	Freedom from Holes	Visual Defects	
				Major	Minor
Inspection Level	S2	S2	G1	G1	G1
AQL	4.0	4.0	1.5	2.5	4.0

Resistance to Permeation by Chemotherapy Drugs

Chemotherapy Drug Tested	Minimum Breakthrough Time (min)
Fentanyl Citrate Injection, 100 mcg/2 ml	>240
Simulated Gastric Acid	>240
Fentanyl Citrate in Gastric Acid, 50/50 ratio	>240
Carboplatin, 10 mg/ml	>240
Carmustine 3.3 mg/ml	14.8
Cisplatin, 1 mg/ml	>240
Cyclophosphamide 20 mg/ml	>240
Dacarbazine, 10 mg/ml	>240
Docetaxel, 10 mg/ml	>240
Doxorubicin HCl, 2 mg/ml	>240
Etoposide, 20 mg/ml	>240
Fluorouracil, 50 mg/ml	>240
Gemcitabine, 38 mg/ml	>240
Ifosfamide, 50 mg/ml	>240
Paclitaxel, 6 mg/ml	>240
Thiotepa, 10 mg/ml	44.7
Vincristine Sulfate, 1 mg/ml	>240

This product has been tested in accordance with ASTM D6978-05(2019) and achieved the performance level as above. Before use, check suitability for the intended use due to the conditions may differ depending on temperature, abrasion and degradation.

UK CA CE FDA 510(K) MDR Class I REGULATION (EU) 2017/745 PPE Category I REGULATION (EU) 2016/425 ASTM D6319 NON STERILE MD

info@oneglovegroup.com