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Midnight Violet 3.5g Nitrile Powder Free **Examination Glove**

Nitrile Powder Free **Examination Glove (ASTM & EN)**

Product Specification

Product Code N035MNV-OC-24FT

Non-Sterile, Powder-Free, Nitrile, Ambidextrous, Examination Glove **Product Type**

contamination between healthcare workers and patients.

This product meets the current version of ASTM D6319, EN 455-1,2,3 and 4, **Product Conformance**

and Customer Requirements / Category III - PPE (EU 2016/425) / EN ISO 21420:2020 / EN ISO 374 / 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, including labelling and packaging, is subject Other Requirements

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

Resistance to Chemical Permeation

	Tested Chemical	Permeation Level EN 16523-1: 2015+ A1: 2018	Mean Degradation EN ISO 374-4: 2019	CAS Number
J	n-Heptane	6	52	142-82-5
K	Sodium Hydroxide 40%	6	- 21.7	1310-73-2
Р	Hydrogen Peroxide 30%	5	43	7722-84-1
Т	Formaldehyde 37%	5	32.8	50-00-0

Permeation Level	1	2	3	4	5	6	
Breakthrough time (min)	>10	>30	>60	>120	>240	>480	

Test acc. to EN ISO 374-5:2016 Protection against Bacteria and Fungi: Pass Protection against Viruses: Pass

Test acc. to EN ISO 374-2: 2014 Specified: Level 2 (AQL<1.5)

Level	AQL
3	< 0,65
2	< 1,5
1	< 4,0

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	М	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	Freedom from Holes	Visual Defects	
Characteristic	Dimension	Physical Properties		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	23.2		
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	67.0		
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.















