



VWR® POWDER-FREE NITRILE EXAMINATION GLOVES

As per the manufacturer, the below product meets the following criteria:

North American Catalog No:	82026-423	
Lot No:	PT18P001	
Description:	VWR Glove Nitrile Pf Xs Pk100	
Date of Manufacturing: November 2018		
Product Shelf Life:	October 2023	
Country of Origin: Indonesia		

Quality System Compliance:

Products are manufactured under FDA510K, ISO 9001:2008, ISO 13485:2003I, CMDCAS Quality System standard and Good Manufacturing Practices. Products are Inspected and controlled through whole production processing in accordance with current applicable product specifications and QC SOP. Inspection records are reviewed and signed off by qualified personnel for product release.

<u>QC Testing:</u> Representative production samples are collected and inspected in accordance with current applicable Product specification:

Meet or exceed ASTM D6319 and ISO 2859 (Sampling table)

<u>Accuracy:</u>	Water tight test: Visual inspection:	Inspection level = G1; Inspection level = G1;	AQL 1.5 AQL 1.5 (critical defects) AQL 2.5 (major defects) AQL 4.0 (minor defects)
	Dimensional: Physical Property: Powder Content:	Inspection level = S2; Inspection level = S2; Inspection level = 5 pieces;	AQL 4.0 AQL 4.0 Average ≤ 2 mg/glove
	Moisture Content: Glove count:	Inspection level = 5 pieces; Inspection level = 5 dispensers;	Average ≤ 2 mg/glove Average ≤ 1% Tolerance 100+/-2 pieces

Product Specification: This product is Class I category device as defined by the FDA in 21CFR parts 807 sub parts C

Material:	Nitrile Butadiene Rubber.
Non- Pyrogenic:	N/A
Dnase & RNase Free Statement:	N/A
Cytotoxicity Statement:	N/A
BSE/ TSE Statement:	N/A
Latex Statement:	This product is not made with natural rubber latex

Signed:

James Techie

Jamie Ethier VP Global Quality VWR, Part of Avantor

Date: January 9, 2019