



VWR® POWDER-FREE NITRILE EXAMINATION GLOVES

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

North American Catalog No:	82026-424	
Lot No:	PT18D002	
Description:	VWR GLOVE NITRILE PF S PK100	
Date of Manufacturing: April 2018		
Product Shelf Life: March 2023		
Country of Origin:	Indonesia	

Quality System Compliance:

Products are manufactured under FDA510K, ISO 9001:2008, ISO 13485:20031, 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.

QC Testing:	 Representative production samples are collected and inspected in accordance with current applicable Product specification: Meet or exceed ASTM D3578 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: Moisture Content: Glove count:	Inspection level = S2; Inspection level = S2; Inspection level = 5 pieces; Inspection level = 5 pieces; Inspection level = 5 dispensers;	AQL 4.0 AQL 4.0 Average ≤ 2 mg/glove Average ≤ 1% Tolerance 100+/-2 pieces	
Product Specification	on: 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:

Londa K. Shine

Linda K. Shine Manager - Supplier Qualification Global Compliance VWR International LLC

Date: April 21, 2018