



## **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:	PT17K103		
Description:	VWR GLOVE NITRILE PF S PK100		
Date of Manufacturing:	August 2017		
Product Shelf Life:	Life: July 2022		
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.

QC Testing:	Representative production samples are collected and inspected in accordance with current applicable Product specification:					
	<ul> <li>Meet or exceed ASTM D3578 and ISO 2859 (Sampling table)</li> </ul>					
<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 Proper Powder Content Moisture Conter Glove count:	t:	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: This product is Class I category device as defined by the FDA in 21CFR parts 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:						

Jonda K Shine

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

Date: August 29, 2017