



## **VWR® POWDER-FREE NITRILE EXAMINATION GLOVES**

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

North American Catalog No:	h American Catalog No: 82026-428		
Lot No:	PT17S007		
Description:	VWR GLOVE NITRILE PF L PK100		
Date of Manufacturing:	December 2017		
Product Shelf Life:	November 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 Prope Powder Conter Moisture Conte Glove count:	nt:	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 $\leq 2$ mg/glove Average $\leq 1\%$ 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 I		le 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:

K. Shine

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

Date: December 10, 2017