



VWR® POWDER-FREE NITRILE EXAMINATION GLOVES

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

North American Catalog No:	82026-426	
Lot No:	PT17J005	
Description:	ion: VWR GLOVE NITRILE PF M PK100	
Date of Manufacturing: July 2017		
Product Shelf Life: June 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 a Product specification:			
	 Meet or exceed A 	STM D6319 and ISO 2859 (Sampling ta	able)	
<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 Specificat	tion: This product is	s Class I category device as defined by	the FDA in 21CFR parts 807 sub parts C	
Material:	Nitr	Nitrile Butadiene Rubber		
Non-Pyrogenic:	N/A			
DNase & RNase Free Statement: N/A				

 BSE/TSE Statement:
 N/A

 Latex Statement:
 This product is not made with natural rubber latex.

N/A

Signed:

Junda K. Shine

Cytotoxicity Statement:

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

Date: July 15, 2017