



## **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 : 82026-423	
Lot No :	PT16L101	
Description :	VWR GLOVE NITRILE PF XS PK100	
Date of Manufacturing : September 2016		
Product Shelf Life : August 2021		
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.

## **<u>QC Testing:</u>** 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:	Inspection level = S2;	AQL 4.0
	Physical Property:	Inspection level = S2;	AQL 4.0
	Powder Content:	Inspection level = 5 pieces;	Average ≤ 2 mg/glove
	Moisture Content:	Inspection level = 5 pieces;	Average ≤ 1%
	Glove count:	Inspection level = 5 dispensers;	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:	Nltrile 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:

nda K. Shine

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

Date : September 20, 2016