Quality Certificate

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 :	PT16P302
Description :	VWR GLOVE NITRILE PF M PK100
Date of Manufacture:	November 2016
Product Shelf Life :	October 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.

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)

Accuracy:

Water tight test:	Inspection level = G1;	AQL 1.5
Visual inspection:	Inspection level = G1;	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 made with natural rubber latex

Signed :

Ken Crossley
Manager
Quality Assurance

Date : December 09, 2016