Quality Certificate

VWR® POWDER-FREE NITRILE EXAMINATION GLOVES

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

North American Catalog No:	82026-430
Lot No:	PT19B209
Description:	VWR Glove Nitrile Pf Xl Pk100
Date of Manufacturing:	February 2019
Product Shelf Life:	January 2024
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:

- Meet or exceed ASTM D6319 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:	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:



Jamie Ethier
VP Global Quality
VWR, Part of Avantor

Date: February 28, 2019