



## VWR® POWDER-FREE NITRILE EXAMINATION GLOVES

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

|                                   |                               |
|-----------------------------------|-------------------------------|
| <b>North American Catalog No:</b> | 82026-430                     |
| <b>Lot No:</b>                    | PT19B108                      |
| <b>Description:</b>               | VWR Glove Nitrile Pf XI Pk100 |
| <b>Date of Manufacturing:</b>     | February 2019                 |
| <b>Product Shelf Life:</b>        | January 2024                  |
| <b>Country of Origin:</b>         | 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

|  |  |
|--|--|
| <b>Material:</b>                         | Nitrile Butadiene Rubber.                          |
| <b>Non- Pyrogenic:</b>                   | N/A  |
| <b>Dnase &amp; RNase Free Statement:</b> | N/A  |
| <b>Cytotoxicity Statement:</b>           | N/A  |
| <b>BSE/ TSE Statement:</b>               | N/A  |
| <b>Latex Statement:</b>                  | This product is not made with natural rubber latex |

**Signed:**



Jamie Ethier  
VP Global Quality  
VWR, Part of Avantor

**Date:** February 28, 2019