



PRODUCTION SPECIFICATION  
POWDER FREE  
NITRILE EXAMINATION GLOVES

File No: SPEC.PFNBR40  
Issue : 12/05/2014  
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**PRODUCT**

Non – Sterile Disposable Powder Free Examination Nitrile Gloves  
Single online chlorinated

**USAGE**

To conduct medical examination, diagnostic and therapeutic procedures to protect patients and users from cross contamination or infection

**ORIGIN**

Vietnam

**MATERIAL**

Nitrile (Carboxylated Butadiene Acrylonitrile)

**SHAPE**

Ambidextrous  
Bead Cuff (roll rim)

**SURFACE**

Finger tip texture

**COLOR**

Blue/ White

**SMELL**

Slightly smell of NBR

**WEIGHT**

4.0 gr (M size)

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**VRG KHAI HOAN JSC**

*Cau Sat Hamlet, Lai Hung Commune, Ben Cat District, Binh Duong Province, Vietnam*

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**QUALITY CHARACTERISTICS**

All listed standards are used in the latest edition

| Description   | ( VRG Khai Hoan)   | ASTM D6319 –EN455 Standard   |
|---|--|--|
| <p><b><u>Physical Dimensions:</u></b><br/>Overall length<br/>Palm thickness (mm)</p>  <p>Thickness – Single Wall (mm)</p>  | <p>240 mm min</p> <p>75 ± 5 (XS)<br/>85 ± 5 (S)<br/>95 ± 5 (M)<br/>105 ± 5 (L)<br/>115 ± 5 (XL)</p> <p>Fingers : 0.09 mm min<br/>Palm : 0.07 mm min<br/>Cuff : 0.06 mm min</p> | <p>240 mm min</p> <p>70 ± 10 (XS)<br/>80 ± 10 (S)<br/>95 ± 10 (M)<br/>110 ± 10 (L)<br/>120 ± 10 (XL)</p> |
| <p><b><u>Biocompatibility:</u></b><br/>Extractable protein content</p> <p>Powder residual</p>   | <p>Free of protein</p> <p>1mg/ glove</p>   | <p>Max 2 mg/ glove</p>   |

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|   |   |  |
|---|---|--|
| <b><u>Physical Properties:</u></b><br>Tensile strength (MPa)  | <b>1. Unaged</b><br><br>Tensile strength: 18MPa min | <b>1.Unaged</b><br><br>Tensile strength: 14MPa min |
| Elongation at break (%)                                       | Force at break: 6N min<br><br>Elongation: 600% min  | Force at break: 6N min<br><br>Elongation: 400% min |
|   | <b>2.Aged</b><br><br>Tensile strength: 20MPa min    | <b>2. Aged</b><br><br>Tensile strength: 14MPa min  |
|   | Force at break: 6N min<br><br>Elongation: 500% min  | Force at break: 6N min<br><br>Elongation: 400% min |
| <b><u>Glove weight (gm):</u></b><br>Tolerance ( $\pm 0.2$ gm) | <b>XS S M L XL</b><br>3.4 3.7 4.0 4.3 4.6           |  |

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### PACKING AND LABELLING

100 pieces per box, 10 boxes per case

200 pieces per box, 10 boxes per cases

Or as per customer's requirement

### CONTROL NUMBER (LOT NO.)

Each packing unit (dispenser box) and outer carton bears a Control Number / Lot Number

The lot number will be as customer's required and/or in house SOP

### SHELF LIFE:

3 years from the manufacturing date

### INTERNAL SAMPLING PLAN

Sampling examination in accordance with ISO 2859

1. Lot no, brand, marking, labeling on packaging materials inspection: Inspection level S2, AQL 4.0
2. Quantity inspection: Inspection Level S2, AQL 4.0
3. Water tight test
4. Visual check
  - Inspection level G1
  - Minor defect : AQL 4.0
  - Major defect: AQL 2.5
5. Dimension check (length, thickness)  
Inspection level S2, AQL 4.0
6. Tensile strength  
Inspection level S2: AQL 4.0 (13 pcs/ size)
7. Powder content  
Sample: 5 pcs/ size

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### **GOOD MANUFACTURING PRACTICE**

The gloves are manufacturing in compliance with ISO 9001, Medical Device 13458

### **STORAGE**

Store in a dry, ventilated area

Avoid direct sunlight, fluorescent lighting, and storage to photocopy equipments, heat, and moisture.

Do not store above 100<sup>0</sup>F (38<sup>0</sup>C) as this will lead to accelerated aging

Long-term storage can result in pleats, stickiness, and early aging of the gloves

Copper ions discolor glove

*END OF DOCUMENT*

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