

BLUGUARD

PRODUCT SPECIFICATION

Nitrile Examination Grade Glove

PRODUCT

Nitrile disposable glove
Examination grade
Non-sterile
Powder-free
Textured surface

Blu Guard®

COUNTRY OF ORIGIN

Malaysia

INTENDED USE

This is a disposable product intended for medical and non-medical purposes

MATERIAL

Nitrile rubber

OUTER SURFACE

No donning powder used

COMPONENTS

Rubber nitrile (NBR)
Potassium Hydroxide
Titanium Dioxide
Sulfur
Organic accelerators
Zinc Oxide

SHAPE

Straight fingers
Thumb and fingers in one plane
Ambidextrous

CUFF

Beaded (rolled rim)

COLOR

Blue

SIZES

Small (S), medium (M), large (L), extra large (XL)

MARKING

Packaging marked to designated size (gloves not marked)

PACKAGING AND LABELING

Reorder Number INIPFT102-INIPFT1119

100 pieces per box, 1000 pieces per case

CONTROL NUMBER (LOT NO.)

Each packing unit (dispenser box) and outer carton bears a control number

EXAMPLE: 328012531NCZ

Key: 3 Fixed code
28 Manufacturing plant
012531 Sales order number
NC Type of glove
Z Size

QUALITY CHARACTERISTICS

All listed standards are used in their latest edition. Current test data on physical properties is available upon request.

DESCRIPTION	SPECIFICATION	ASSURANCE ACTION
<u>Dimensions</u> <i>Overall length</i> <i>Width</i> <i>Thickness (single wall)</i>	240 mm min 84 mm +/- 3 mm (S) 94 mm +/- 3 mm (M) 105 mm +/- 3 mm (L) 113 mm +/- 3 mm (XL) <i>Finger:</i> 0.09 mm/3.6 mils max. <i>Palm:</i> 0.07 mm/2.8 mils max. <i>Cuff</i> 0.06 mm/2.4 mils max.	<i>ASTM D 6319</i>
<u>Biocompatibility</u> <i>Inside pH</i>	7.0 +/- 1	<i>Test method A1</i>
<u>Physical properties</u> <i>Tensile strength (before aging)</i> <i>(after aging)</i> <i>Elongation (before aging)</i> <i>(after aging)</i>	<i>33 MPa max.</i> <i>31 MPa max.</i> <i>890% max.</i> <i>891% max.</i>	<i>ASTM D 412</i>

PERFORMANCE REQUIREMENTS FOR QUALITY CHARACTERISTICS

For reference purpose in accordance with ISO 2859 "Sampling Procedures for Inspection by Attributes"

INTERNAL ATTRIBUTIVE RELEASE INSPECTION

Sampling for examination in accordance with ISO 2859-1.

Unit for *inspection*: one (1) glove

If several defects are found on one glove, only the most serious defect (i.e. lowest category) is evaluated

The acceptance criteria is based on the number of defectives observed in a sample

FINAL GLOVE RELEASE

Assurance action

ISO 2859-1: "Sampling Procedures for Inspection by Attributes – Part 1: Sampling Schemes Indexed by Acceptance Quality Limit (AQL) for Lot-by-Lot Inspection"

Sampling inspection and final release information

Major defects: highest concern non-conformities which prevent correct use of the product. AQL 4.0 (inspection level GI for leaks)

PACKAGING, MARKING, GOOD DELIVERY INSPECTION

Assurance Action

Set-up and patrol inspection at packaging
Supervision of vehicle or vessel loading

GOOD MANUFACTURING PRACTICE

The gloves are manufactured in compliance with ISO 9001 and ISO 13485

STORAGE

According to ISO 2230 for Vulcanized Rubber

Store in a dry, ventilated area

Avoid direct sunlight, fluorescent lighting, heat, and moisture

Do not store above 100° F (38° C) as this will lead to accelerated aging

Long-term storage can result in pleats and stickiness

END OF DOCUMENT