

## SPECIFICATION

**PRODUCT** Disposable Nitrile Glove, Blue, Powder free

**INTENDED USE** For medical examination, food preparation, industrial use

**MATERIAL** Nitrile, this product does not contain Proteins found in Natural Rubber goods.

**SURFACE TREATMENT** Halogenation / siliconization and extensive washing in water. Inside coated with synthetic material.

**SHAPE** Straight fingers, thumb and fingers in one plane, fits either hand (ambidextrous) Rolled rim

**SIZES** Small (S), Medium (M), Large (L), X-Large (XL)

**COLOR** Blue

**MARKING** Gloves are not marked to designated size.

### Vigilance and Reporting system of MDR

This document and its contents are confidential. Do not copy, discuss with or give access to people not designated.

### QUALITY CHARACTERISTICS

Every mentioned standard is used in the latest edition.

DESCRIPTION	SPECIFICATION	TEST METHOD
BARRIER PROPERTIES Freedom from holes	AQL 1.5	EN455-1
BIOCOMPATIBILITY Powder residue on powder free gloves	$\leq 2$ mg / glove	EN455-1
PHYSICAL PROPERTIES Tensile Strength Before Aging/After Aging Elongation Before Aging/After Aging	Min 11 / 9MPa Min 300%/300%	EN455-2

DIMENSION Hand-width is size related	Size related table Issued on request S: 85±5 mm. M: 5±5mm. L: 105±5mm. XL: 115±5 mm	EN455-2
Total length	Min 240 mm	EN455-2
Storage temperature	Max 40°C Min -5°C	EN455-2
Single Wall thickness Finger palm	Min 0.05 mm. Min 0.05 mm.	EN455-2

## PERFORMANCE REQUIREMENTS FOR QUALITY CHARACTERISTICS

In accordance with ISO 2859 "Sampling Procedures and Tables for Inspection by Attribute" All standards listed in this specification are applied to medical gloves non-sterile.

## PRODUCTION ATTRIBUTIVE RELEASE INSPECTION

Sampling for inspection in accordance with ISO 2859 (unit 1 glove).

## FINAL GLOVE RELEASE PACKAGING; MARKING; CONTAINER DELIVERY INSPECTION

### Assurance action following the latest edition of the standards.

ASTM D 6319 "Standard Specification for Nitrile Examination Gloves for Medical Application" Set-up and patrol inspection (in process) at packaging and labeling. Supervision and stuffing records of vehicle or vessel loading.

## SAMPLING INSPECTION AND FINAL RELEASE INFORMATION

### Major defects

(pinholes enclosed-Inspection level G I for leaks) highest concern are non-conformities which prevent correct use of the product. AQL 1.5 for pinholes.

### Minor defects

(Inspection level G I for visual defects aggregated) are non-conformities of lower degree of concern, which do not prevent correct use of gloves.

### AQL 1.5 GOOD MANUFACTURING PRACTICE

The gloves are manufactured in compliance with ISO 9001, ISO13485

This documents and its contents are confidential. Do not copy, discuss with or give access to people not designated.

## MICROBIOLOGICAL CLEANLINESS CONTROL

---

The bioburden of the finished gloves are monitored and recorded. Unusual contaminants are identified. It is attempted to determine their sources and eliminating or reducing their impact. Tests are performed by an approved Institute for Microbiological Control.

**CAUTION:** Non-sterile examination gloves are used in a variety of circumstances, including procedures where the surface of the glove contacts wounds, body cavities, or other possible routes of contaminating. If conditions warrant, the user may wish to minimize the risk of infection. In this case we recommend the decontaminating of the gloves prior to use by disinfectants or other effective methods

### **CERTIFICATES**

A Certificate of Compliance with this specification can be issued only together with order.

### **STORAGE**

Keep storage area cool, dry and dust free, avoid ventilation and storage close to photocopy equipment. Copper ions discolor the glove. Protect gloves against ultraviolet light sources, as sunlight and oxidizing agents. Storage above 86°F (30°C) will lead to accelerated aging and should be avoided under any circumstances. Long term storage in bulk can lead to pleats, stickiness and early aging of the glove and should be avoided.

This documents and its contents are confidential. Do not copy, discuss with or give access to people not designated.