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TECHNICAL PRODUCT-DESCRIPTION

PRODUCT

Disposable Nitrile Glove, Black**, Powder**

free INTENDED USE

Medical activities expect surgery where presence of glove powder should be avoided.

MATERIAL

Nitrile . This product dose not contain Proteins found in Natural Rubber

goods. SURFACE TREATMENT

Halogenation / siliconization and extensive washing in water.

Inside coated with synthetical material.

SHAPE

Straight fingers, thumb and fingers in one plane, fits either hand (ambidextrous)

Rolled rim

SIZES

Small (S), Medium (M), Large (L),XLarge (XL)

COLOR

Black

MARKING

Gloves are not marked to designated size.

Vigilance and Reporting system of MDR

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QUALITY CHANRACTERISTICS

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	≤ 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 XS: 75±5 mm	EN455-2

	S: 85±5 mm. M: 95±5 mm. L: 105±5 mm. XL: 115±5 mm	
Total length	Min 240 mm	EN455-2
Storage temperature	Max 40° C Min -5° C	EN455-2
Single Wall thickness Finger palm	Min 0.10 mm. Min 0.08 mm.	EN455-2

PERFORMANCCE REQUIREMENTS FOR QUALITY CHARACTERISTICS

In accordance with ISO 13485"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 1 3 4 8 5 (unit 1 glove).

SAMPLING INSPECION AND FINAL RELEASE INFORMATION

Major defects (pinholes enclosed-Inspection level G l for leaks) highest concern are

non-conformities which prevent correct use of the product. AQL 1.5 for pinholes

Minor defects (Inspection level G l 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, ISO 13485

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MICROBIOLOGICAL CLEANLINESS CONTTROL

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 on request 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.