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TECHNICAL PRODUCT-DESCRIPTION FOR STA

FILE NO: US- NCMC-2FB

PRODUCT

LATEX Examination Glove, powder free

Medical grade, Extra rough (Textured)at finger tip, non sterile

INTENDED UES

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

MATERLAL

Natural rubber latex

Warning: This product contains natural rubber latex which may cause allergic reactions.

SURFACE TREATMENT

Modified Cornstarch according to EN 455-3 no Talcum (free of Magnesiumsilicate).

Donning powder caution:

If conditions warrants, the user may wish to remove residual powder from the gloves prior to use in order to minimize the potential for adverse effects.

Caution: Users should consider the circumstances of use in deciding whether to remove residual powder on gloves after donning. Powder can be removed by wiping gloves thoroughly with a sterile wet sponge, sterile wet towel or other effective methods.

AHAPE

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

Rolled rim

SIZES

Small (S), Medium (M), Large (L), Extra large (XL)

COLOR

Natural - white

MARKING

Gloves are not marked to designated size.

Vigilance and Reporting system of MDD

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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	EN 455-1
BIOCOMPATIBILITY Powder on Gloves	≤2 mg/Glove	EN 455-3
PHYSICAL PROPERTIES Force at break before / after aging (N) Tensile strength before/after	EN 455-2 Median 6.0 N / 6.0 N Min 18 /14 MPa	EN 455-2

aging (MPa) Ultimate elongation bef./after aging(%)	Min 650% / 500%	
DIMENSION Hand-width is size related	EN 455-2 Size related table issued on request XS: ≤ 80 mm. S: 80±10 mm. M: 95±10 mm. L: 110±10 mm. XL: ≥110 mm.	EN 455-2
Total length	EN 455-2 Median 240 mm. All size	EN 455-2
Single Wall thickness Finger palm	EN 455-2 Min 0.09 mm. Min 0.09 mm.	EN 455-2

PERFORMANCCE REQUIREMENTS FOR QUALITY CHARACTERISTICS

In accordance with ISO 2859-1” 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; CONTAINEER DELIVERY INSPECTION

Assurance action following the latest edition of the standards.

EN 455-1 “Medical gloves for single use Part 1; Specification for freedom from holes”.

EN 455-2 “Medical gloves for single use Part 2; Requirements and testing for physical properties”.

EN 455-3 “Medical gloves for single use Part 3; Requirements and testing for biological evaluation”.

ASTM D 3578 “Standard Specification for Rubber Examination Gloves”

Set-up and patrol inspection (in process) at packaging and labeling.

Supervision and stuffing records of vehicle or vessel loading.

SAMPLING INSPECION AND FINAL RELEASE INFORMATION

Major defects (pinholes enclosed-Inspection level G l for leaks) highest concern are non-c onformities 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 ≤4.0

GOOD MANUFACTURING PRACTICE

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

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 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.