

SAFETY DATA SHEET

SECTION 1: IDENTIFICATION

Product Identifier

Textured Nitrile Medical Examination Gloves, Powder Free

Intended Use

Textured Nitrile Medical Examination Gloves are single use device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner

Restricted Use

Do not use for handling organic solvents

Other Means of Identification

AMD Medicom Item Code(s): List of Products in Annex

Company Address

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SECTION 2: HAZARD IDENTIFICATION

Biological Hazards

Components used in glove manufacturing may cause allergic reaction in some user

Hazards related to the re-use of the medical device

Re-use of the non-sterile single use medical glove may lead to:

- Loss of product lot traceability
- Risk of contamination and infection increases due to improper cleaning process

Damages / weakening by the cleaning processes leading to increased risk of holes and tear during re-use

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Acrylonitrile Butadiene Rubber, Sulfur, Accelerators, Zinc Oxide, Potassium Hydroxide, Titanium Dioxide, Blue Pigment

SECTION 4: FIRST AID MEASURES

No first aid measures required, as glove is non-hazardous

SECTION 5: FIRE FIGHTING MEASURES

Extinguishing Media: Foam, Carbon Dioxide and Water

Flash Point: Not Applicable

SECTION 6: ACCIDENTAL RELEASE MEASURES

None

SECTION 7: HANDLING AND STORAGE

The product should be stored in a cool dry place avoiding exposure to direct sunlight, high temperature and humidity

After the package is open, direct sunlight, fluorescent lighting and devices generating ozone should be avoided, and the product should be kept away from X-ray apparatus

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Do not store these gloves with organic solvents as these solvents can degrade the gloves
Ventilation is not necessary under normal storage condition

SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION

None

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Textured Nitrile Medical Examination gloves meet the **ASTM D6319 Standard**

Form: Soft solid form

Color: Blue

SECTION 10: STABILITY AND REACTIVITY

Stability: Stable

Condition to avoid: None

Incompatible Material: None

SECTION 11: TOXICOLOGICAL INFORMATION

Animal safety test for potential skin irritation and delayed skin sensitization showed that the glove is neither a skin irritant nor potential skin sensitizer

SECTION 12: ECOLOGICAL INFORMATION

Not Applicable

SECTION 13: DISPOSAL CONSIDERATIONS

Textured Nitrile Medical Examination are non-biodegradable product where special decommissioning or disposal is required

SECTION 14: TRANSPORT INFORMATION

No special transportation requirements

SECTION 15: REGULATORY INFORMATION

Nitrile Examination Gloves are manufactured under following Quality Management System:

- ISO 13485
- CAN/CSA ISO 13485
- ISO 9001
- US FDA QSR

SECTION 16: OTHER INFORMATION

Legal disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. AMD Medicom Inc. shall not be held liable for any damage resulting from handling or from contact with the products listed in Annex.

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ANNEX: LIST OF PRODUCTS

No.	Description
OPL-DY2	DYNAMIC NITRILE PF L
OPM-DY2	DYNAMIC NITRILE PF M
OPS-DY2	DYNAMIC NITRILE PF S
OPXL-DY2	DYNAMIC NITRILE PF XL
OPXS-DY2	DYNAMIC NITRILE PF XS
OPL-BL2	BLUE LITE NITRILE PF L
OPM-BL2	BLUE LITE NITRILE PF M
OPS-BL2	BLUE LITE NITRILE PF S
OPXL-BL2	BLUE LITE NITRILE PF XL
OPXS-BL2	BLUE LITE NITRILE PF XS