

**Nitrile Examination Gloves-Powder free Non-Sterile**

**DEVICE INTENDED USE:**

It is used to protect the patient and users from cross infection during examination, check-up, treatment and handling of contaminated medical materials except for surgery.

**DEVICE NAME, CATALOGUE NO AND BRAND NAME:**

Device Name	Catalogue no.	Brand Name
Nitrile Examination Gloves	EXMNUN	NULIFE, NUFIT, NUFLOW, MEDI-AID, NURAZ, DEN-V, PREMIER CARE, SANTE, SFM, BB , CARE GLOVES, SUPREME, BENESIT, SAFETEX, STARGLOVE

**DEVICE SIZES:**

Device Name	Sizes
Nitrile Examination Gloves	Extra-Small, Small, Medium, Large, Extra-Large

**BASIC UDI:**

8905159EXMNPf99

**DEVICE DESCRIPTION:**

**Nitrile Exam Gloves – Powder free, Non-Sterile**

A disposable device made of nitrile intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. Non-sterile medical examination gloves, which may or may not be anatomically shaped. These gloves are powder free. Examination gloves are intended for conducting medical examinations, diagnostic and therapeutic procedures and for handling contaminated medical material. Nitrile gloves are preferred option for person with latex allergy.

**INTENDED USER:**

Healthcare professionals.

**TARGET PATIENT POPULATION:**

These Nitrile gloves are used for all patient population for examination / diagnostic purpose only.

Rev. No.	<b>A</b>	Rev. Date	01/06/2023	Doc No:	MRK/IFU/NTR-EXM/PF	Page 1 of 5	Device Name	Nitrile Examination Gloves, Non-Sterile Powder free
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## **Nitrile Examination Gloves-Powder free Non-Sterile**

### **DEVICE SHELF LIFE:**

5 years from the date of manufacture printed on the product label.

### **STORAGE INSTRUCTION:**

It is recommended to store the gloves in cool, dry place, in the temperature range of 5°C to 40°C and to protect them against direct sunlight.

### **INDICATIONS:**

- Protection of the wearer from contamination with blood, secretions, and excretions and the associated risk of contamination with pathogens capable of reproduction.
- Prevention of pathogen release from the hand into the exam site.
- Defined pathogen barrier as protection from biological agents.

### **CONTRAINDICATION:**

Gloves might contain ingredients which may cause allergies in sensitised person, who may develop irritant and/or allergic contact dermatitis.

### **WARNINGS AND PRECAUTIONS:**

1. Do not use after the expiry date printed on the label.
2. Do not use it if the package is opened or damaged. Use of product whose package is opened, or damage may cause infection.
3. Do not reuse. The reuse of the gloves may cause severe complications such as cross contamination, dermatitis, loss of physical properties, infection, and poor barrier protection.
4. Single Use mentioned on Sales Packaging Label.
5. Device should not be stored in direct sunlight
6. Device disposable should be done as per local regulatory norms.

### **DIRECTION FOR USE:**

- Select the appropriate size Gloves for the hand.
- Take out the Gloves from the box.
- Do not wear rings or other ornaments before wearing them.
- Keep your hands dry so that the gloves fit your fingers.
- Wear gloves.
- Must check the date of manufacturing and expiry date before use.
- Adjust the gloves as needed.

#### **A) How to Don Gloves:**

- Rubbing the hand with alcohol or wash with water
- Dry hands before donning the gloves.
- Take out gloves from box.
- Gloves need to be donned carefully; do not apply excessive force to pull the gloves when donning.

Rev. No.	<b>A</b>	Rev. Date	01/06/2023	Doc No:	MRK/IFU/NTR-EXM/PF	Page 2 of 5	Device Name	Nitrile Examination Gloves, Non-Sterile Powder free
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- Keep the fingernails short and change gloves frequently to avoid tearing issue.

**B) How to Remove Gloves:**

- The gloves should be discarded with an appropriate waste disposal container after use according to local disposal regulations

**DURATION OF USE:**

Duration of Use is transient (Less than 60 minutes)

**CLINICAL BENEFITS:**

- Nitrile gloves are highly puncture resistant.
- Nitrile's high tensile strength allows the gloves to stretch more than latex and vinyl.
- Nitrile gloves provide lower rates of perforation and lower viral leakage rates.
- Nitrile gloves are chemically resistant.
- The gloves' tactile sensitivity allows the user to move freely and perform delicate tasks.
- Nitrile gloves have good barrier integrity.
- Nitrile gloves have good fit and comfort.

**SIDE EFFECTS:**

Redness, burning sensation, irritation, sensitization, itches, hives.







**RESIDUAL RISK:**

1. Infection
2. Allergic Contact Dermatitis

**DEVICE PACKAGING CONTAINS:**

Nitrile Examination Gloves Powder free Non Sterile	100 / 200 pcs
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**SYMBOLS USED IN DEVICE SINGLE UNIT PACKAGING AND SALES PACKAGING**

	Manufacturer		Date of Manufacture		Keep away from Sunlight
	Authorized Representative in the European Community/ Authorized representative		Use by Date/ Expiry Date		Keep Dry

Rev. No.	<b>A</b>	Rev. Date	01/06/2023	Doc No:	MRK/IFU/NTR-EXM/PF	Page 3 of 5	Device Name	Nitrile Examination Gloves, Non-Sterile Powder free
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**Nitrile Examination Gloves-Powder free Non-Sterile**

	European Union				
	Latex Free		Lot. No.		Do not Re-use / Use only once
	CE Mark Symbol		Do not use if package is damaged and consult instructions for use		Caution
	Medical Device		Non sterile		Storage Temperature
	Unique Device Identifier				

**Notice:**

In case of any serious incident that has occurred in relation to the device, contact manufacturer (MRK Healthcare Pvt Ltd) or authorized representative and competent authority of the member state where user/ patient is established without any delay or within 24 hrs.



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Authorized EU REP

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MRK HEALTHCARE PVT. LTD.

IFU

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### Revision History

Rev. No.	Date	Reason for Revision
A	25/05/2023	Initial Release