INSTRUCTION FOR USE

As per requirement of Medical Device Regulation (EU) 2017/745

Product Name: Sterile Latex Surgical Gloves: Pre- Powdered
Brand Names: Dr. Glove
Class IIa, Rule 06 as per Annex VIII of MDR 2017/745

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Product Name: Sterile Latex Surgical Gloves: Pre- Powdered
Brand Names: DR.GLOVE

Description of the Device

The powdered latex surgical gloves are disposable device made up of natural rubber latex. Gloves provide barrier protection to both patients and health care workers against exchanging microorganisms through their hands and body fluids. Because of the excellent elasticity, durability, tactile properties, low microbial/fluid penetration rate and low cost, natural rubber latex (NRL) gloves have been most widely used.
Surgical gloves have more precise sizing with a better precision and sensitivity and are made to a higher standard. The gloves are designed and available in specified sizes as of anatomically shaped. The sterile latex surgical gloves appear in natural white color and micro rough textured in the palm area.

Intended Use

The sterile latex surgical gloves are intended to prevent contamination of the patient during invasive procedures and the user to protect their hand from exposure to potentially infectious materials.

Size Variants in French Size

Size - 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0

Length - Min. 270mm

Duration of Use

Duration of use is Transient (<60 minutes),

Note: Users have to change the gloves hourly once if the surgery takes more than 1 hour.

Directions For Use

Direction to wear the surgical gloves

- Perform hand hygiene, and then select the appropriate size of sterile gloves. Remove gloves one at a time out of the box, touching only the top of the cuff.
- Put hand through opening and pull up to the wrist.
- Repeat procedure with the second hand.
- Adjust gloves to cover wrists as required.

Direction to remove the surgical glove

- Grasp glove on the outside about 1/2 inches below the cuff (edge of the glove opening). Do not touch the wrist with the other hand.
- Pull down glove, turning it inside out. Hold the inside-out glove in the gloved hand.
- Gather the inside-out glove in the gloved hand.
- Insert finger of the bare hand under the cuff of the gloved hand.
- Pull down the glove until it is inside out, drawing it over the first glove.
- Discard gloves in a garbage container (This step reduces the spread of microorganisms).

Operating Instructions

- When wearing gloves change or remove gloves in the following situations: During patient care if moving from a contaminated body site to another body site (including a mucous membrane, non-intact skin or a medical device with in the same patient or the environment).
- In case of any allergic reaction, medical aid should be sought immediately.
- Use of petroleum-based hand lotions or creams may adversely affect the integrity of latex gloves and some alcohol-based hand-rubs may interact with residual powder on health-caseworker's hands.
- After donning remove powder by wiping gloves thoroughly with a sterile wet sponge or sterile wet cloth or other effective method.
- Surface powder should be removed aseptically prior to undertaking operative procedures in order to minimize the risk of adverse tissue reactions.

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 surgical Site during surgery.
- Defined pathogen barrier as protection from biological agents.

Contraindications

- Latex gloves are made of Natural rubber latex, which might cause allergic reactions including Latex Allergy – Anaphylaxis if the user is allergic to latex.
- Gloves contain Natural Latex; persons who are sensitive to Latex should consult a physician before using.
- Powder Allergy

Precautions & Warnings

This product contains natural rubber latex which may cause

- Allergic reactions
- Contents sterile unless package is damaged or wet.
- Away from direct sunlight and ozone.
- Do not reuse, reuse can cause cross infection and compromise safety.
- Do not re-sterile
- If the gloves are worn for a longer use ie more than 60 minutes then change the gloves after every one hour.
- Reprocessing like Re- sterilization are not recommended and should be avoided, this can compromise the product performance.

Intended User

Healthcare Surgeons, Operation Theatre Personnel and Healthcare providers for the patients at high risk of infections.

Target Patient Population

It can be used in all patient population except in patients with known allergy to natural latex rubber.

Clinical Benefits

NRL gloves or Natural Rubber Latex Gloves are:

- Competent barrier to protect against infections for both healthcare professionals and the patients.
- Provide lower rates of perforation and lower viral leakage rates.
- Are easy to put on comfortable to wear and provide adequate, durable protection.
- Have good barrier integrity.
- Have less after-use defects.
- Has significant greater satisfaction with regard to factors such as quality, safety and durability.
- Have high tear propagation strength.
- Have higher perforation rate.
- Have high tensile strength.
- Have good fit and comfort.

Residual Risks

- Infection (Blood-Borne Infection, Post-operative wound infection, Surgical Site Infection)
- Type-I Allergy, Anaphylaxis
- Powder Allergy (Powder induced granulomas, dyspnea due to powder allergy, respiratory diseases)
- Inflammation
- Toxic to environment

Side effects

- Itching
- Temporary discomfort
- Skin irritation on the patient
- Skin inflammation
- Latex Allergy
- Powder Allergy

Storage Instruction

It is recommended to store the gloves in dry place, in the temperature of 5°C -30°C and to protect them against direct sunlight and fluorescent light.

Disposal Instructions

- Used gloves can be contaminated with contagious or other hazardous substances. They should be disposed of in accordance with local regulation.
- Gloves should be buried or burned under controlled conditions.

How Supplied

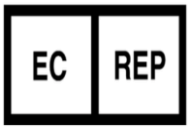
- Gloves supplied as 1 pair per pouch
- Color of the gloves Light creamy

Method of sterilization

Sterilized Using Ethylene Oxide Gas

Shelf life

3 years (from the date of manufacturing)

Symbol	Title of Symbol	Description
	Consult Instructions for Use	Indicates the need for the user to consult the instructions for use.
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Do not use if Package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
	Authorized Representative in European Community	Actor ID/SRN:ES-AR-000000293 **CMC Medical Devices & Drugs SL** Address:C/ Horacio Lengo N18, 29006 Málaga Email:info@cmcmedicaldevices.com Telephone number:+34 951214054 Country:Spain
	Manufacturer	Vijayalakshmi Health and Surgicals Pvt Ltd 406, APIIC Growth Centre, GundlaPalli,Ongole, Prakasam District-523211, AndhraPradesh,INDIA.
	CE Mark	A CE Mark is a symbol that must be affixed to many products before they can be sold on the European market.
	Keep Dry	Indicates a medical device that needs to be protected from moisture.
	Keep away from sun light	Indicates a medical device that needs protection from light sources.
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.

	Sterilized by ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.
	Do not resterilize	Indicates a medical device that is not to be resterilize.
	Contains or presence of latex rubber	Indicates the presence of natural rubber or dry natural rubber latex as a material of construction within the medical device or the packaging
 UDI Code	Unique Device Identification	A unique device identifier (UDI) is a unique numeric or alphanumeric code that generally consists of the following: Device identifier (DI), a mandatory, fixed portion of a UDI that identifies the label and the specific version or model of a device.
	Sterile Barrier	Indicates to ensure the sterility of the product
	Medical Device symbol	Indicates to that the device is medical device group.
	Manufacturing Date	Indicates that the medical device manufacturing date
	Expiry date	Indicates that the medical device the expiry date
	Lot Number	Indicates that the medical device lot numbering system
	Warning/Caution	Indicates that the medical device warning
	Country code symbol	Indicates that the medical device country code

UDI No:

Export: 890615299LSG-PP-E9K

Domestic: 890615299LSG-PP-D9H