

	AMAZING RUBBER PRODUCTS PVT LTD	Doc. No.	ARP/LSG-PD/IFU
		Revision No.	02
	INSTRUCTION FOR USE	Effective Date	19/08/2022
	Sterile Latex Surgical Gloves Powdered	Page No.	1 of 5

1. Name of the Device:

Sterile Latex Surgical Gloves Powdered

2. Brand Name:

AMCARE, AMAZING & SAFE N CARE

3. Name and Address of the manufacture:

AMAZING RUBBER PRODUCTS PVT.LTD.
 Plot No.:14C, CSEZ, KAKKANAD,
 Cochin, Kerala, India, Pin Code- 682037
 Phone: +91 9447053062
 Email: info@amazingglove.com
 Website: www.amazingglove.com

4. Unique Device Identification (UDI):


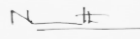

#	Product Name	Size/Variant	Basic UDI-DI
1.	The Sterile Latex Surgical Gloves – Powdered	5½	8908012547LSGPP5.58K
		6	8908012547LSGPP6.08E
		6½	8908012547LSGPP6.58Q
		7	8908012547LSGPP7.08K
		7½,	8908012547LSGPP7.58V
		8	8908012547LSGPP8.08Q
		8½	8908012547LSGPP8.592
		9	8908012547LSGPP9.08V

5. Intended Use:

The Sterile Latex Surgical Gloves – Powdered are intended to be worn by the operation theatre personnel hands during surgical procedures to protect surgical wound from contamination and to provide barrier against potentially infectious materials and other contaminants such as body fluids. Also, helps to prevent cross-contamination between caregivers and patients. It is sterilized with EO and is for Single use.

6. Product Description

Latex Surgical gloves – Powdered are sterile, disposable and are used by personnel working in operation theatres to prevent cross-contamination between caregivers and patients. These gloves are

	Name	Function	Signature	Date
Prepared By	Jayabarathi. S	RA/QA		19/08/2022
Reviewed By	Neethu Joseph	QA		19/08/2022
Approved By	Georgekutty Manuel	Managing Director		19/08/2022

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made up of Natural Rubber Latex. Our Latex Surgical gloves – Powdered have more precise sizing with a better precision and sensitivity and are made to ASTM D3577-09, EN 455 and IS 13422 requirements. The gloves are powdered and treated for low protein to minimize allergic reactions. Available in 5.5 to 9.0 sizes. The latex surgical gloves – powdered are sterilized by gaseous method with Ethylene Oxide gas. The Latex Surgical Gloves – Powdered are packed in a sterility maintenance package to ensure the shelf life of 05 years.

7. Device Constituents/material:

#	Raw Material Name	Material Use
1.	Natural Rubber Latex (60% DRC)	Base Material
2.	Zinc salt of mercaptobenzothiazole (ZMBT)	Accelerator
3.	Zinc Diethyldithiocarbamate (ZDEC)	Accelerator
4.	Condensation product of dicyclopentadiene and p-cresol	Antioxidant
5.	Titanium Dioxide (TiO ₂)	Color pigment
6.	Sulphur (S)	Vulcanizing
7.	Zinc oxide (ZnO)	Activator
8.	Salt of polymer Naphthalene sulphonic Acid condensation (Tamol)	Dispersing Agent
9.	Corn starch	Dusting powder
10.	Calcium carbonate (CC)	Coagulant
11.	Calcium Nitrate (CN)	Coagulant
12.	Polyethylene Oxide condensate (Teric)	Surfactant
13.	Nitric Acid (HNO ₃)	Mould Cleaning Agent

8. Product Sizes:


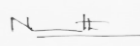

5½, 6, 6½, 7, 7½, 8, 8½, 9 inches

9. Operating Instructions:

- Select the appropriate size Gloves for the hand.
- Take out the Wallet from the pouch by peeling it off at the site of direction for open.
- Wear the gloves as left to the Left hand & Right to the Right Hand as denoted on the wallet.
- Must check the date of manufacturing and expiry date
- Adjust the gloves as needed.

10. Storage Condition

Storage condition of Sterile Latex Surgical Gloves Powdered is 5 to 27°C.

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11. Duration of use

Duration of use is transient (<60 minutes).

12. Precautions & Warnings:

- Do not Re-sterilize – Re-sterilization can cause product damage / Contamination
- Do not Re Use - Reuse can cause Contamination which can lead to serious infections
- After donning remove powder by wiping gloves thoroughly with wet sterile cloth/sponge or other effective method.

13. 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

14. 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 with Powder content, persons who are sensitive to Latex and or Powder should consult a physician before using

15. Intended User:

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


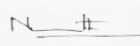

16. Patient Population:

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

17. Clinical Benefits:

NRL or Natural Rubber Latex Gloves:

- Provide 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.

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- 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 high tensile strength
- Have good fit and comfort

18. Residual Risk:

- Anaphylaxis
- Blood-Borne Infection, Post-operative wound infection
- Respiratory Diseases
- Inflammation
- Toxic to environment

19. Side Effects:

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

20. Method of Sterilization:


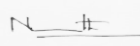

Sterile Latex Surgical Gloves – Powdered is supplied as sterile product and the sterilization type is Ethylene oxide

21. Disposal instructions:

- Gloves after usage remove gently & carefully.
- Discard as per the Statutory & regulations laws.


22. How Supplied:

- The Colour of the gloves milky white.
- Gloves are supplied as pair in each unit of packing.

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23. Explanation of symbols used on label:

					
Do not Re-sterilize	Do not use if package is Damaged	Instructions for Use	Sterilized using Ethylene Oxide	Do not Re Use	Storage Conditions
					
Latex	Caution	Keep Away from Sunlight	Keep Dry	Lot / Batch No.	Date of Manufacture
					
Use by Date	CE Logo	Single sterile barrier system	Unique Device Identification	Medical Device	Non-Pyrogenic

Manufacturer



Amazing Rubber Products Pvt. Ltd
Plot No. 14C, Cochin Special Economic Zone
Kakkanad, Cochin-682 037, Kerala, India
@infoamazingglove.com, www.amazingglove.com


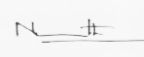

EAR Address



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Monchengladbach, Germany
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Ph.: +49 (0) 2161 990 883 1

24. Revision History

Revision No	Changes Incorporated	Effective Date
00	Initial Release	07/07/2021
01	Updated duration of use and storage temperature range as per TR comments	25/03/2022
02	Updated section 7 as per TR2 comments	19/08/2022

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