

	AMAZING RUBBER PRODUCTS PVT LTD	Doc. No.	ARP/LSG-PF/IFU	
		Revision No.	02	
	INSTRUCTION FOR USE		Effective Date	19/08/2022
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1. Name of the Device:

Sterile Latex Surgical Gloves Powder Free

2. Brand Name:

Amazing+, Amcare+, SafeNcare+

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):

Sl.No	Product Name	Size/Variant	Basic UDI-ID
1.	Sterile Latex Surgical Gloves – Powder Free	5½	8908012547LSGPF5.56D
		6	8908012547LSGPF6.068
		6½	8908012547LSGPF6.56J
		7	8908012547LSGPF7.06D
		7½,	8908012547LSGPF7.56P
		8	8908012547LSGPF8.06J
		8½	8908012547LSGPF8.56U
		9	8908012547LSGPF9.06P

5. Intended Use:

The Sterile Latex Surgical Gloves – Powder Free 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. Latex Surgical Gloves – Powder Free is sterilized with EO and Single use.

	Name	Function	Signature	Date
Prepared By	Jayabarathi. S	RA/QA		19/08/2022
Reviewed By	Shyam Pillai	Post-production		19/08/2022
Approved By	Jayasankar. S	Director		19/08/2022

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6. Product Description:

Latex Surgical gloves – Powder Free are sterile, disposable and are used by personnel working in operation theatres to prevent cross-contamination between caregivers and patients. These gloves are made up of Natural Rubber Latex. Our Latex Surgical gloves – Powder Free 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 Powder Free and treated for low protein to minimize allergic reactions. Available in 5.5 to 9.0 sizes. The latex surgical gloves – Powder Free are sterilized by gaseous method with Ethylene Oxide. The Latex Surgical Gloves – Powder Free are packed in a sterility maintenance package to ensure the shelf life of 3 years.

7. Device Constituents/material:



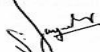
#	Raw Material Name	Material Use
1.	Natural Rubber Latex (60% DRC)	Base Material
2.	Zinc salt of mercaptobenzothiazole (ZMBT)	Accelerator
3.	Zinc Diethyldithiocarbamate (ZDEC)	Accelerator
4.	Condensation product of dicyclopentadiene and p-cresol	Antioxidant
5.	Titanium Dioxide (TiO ₂)	Color pigment
6.	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.

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10. Storage Condition

Storage condition of Sterile Latex Surgical Gloves Powder Free is 5 to 30°C.

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

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 limited content of Powder; persons who are sensitive to Latex 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:

- Protect against infections for both healthcare professionals and the patients.
- Provide lower rates of perforation and lower viral leakage rates.
- 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 Risks:

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

19. Side Effects:

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

20. Method of Sterilization:



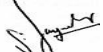
Sterile Latex Surgical Gloves – Powder Free is supplied as sterile product and the sterilization type is Ethylene oxide.

21. Disposal Instructions:

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






22. How Supplied:

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

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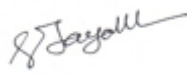

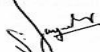
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23. Explanation of symbols used on label:

					
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		
	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 Europecert, Alstr 97, 41063 Monchengladbach, Germany Email: support@europecert.eu 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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