

	<b>AMAZING RUBBER PRODUCTS PVT LTD</b>	Doc. No.	ARP/LGG-PD/IFU	
		Revision No.	04	
	<b>INSTRUCTION FOR USE</b>		Effective Date	25/11/2023
	<b>Sterile Latex Gynaecological Gloves Powdered</b>		Page No.	1 of 5

1. Name of the Device:

Sterile Latex Gynaecological Gloves Powdered

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](mailto:info@amazingglove.com)

Website: [www.amazingglove.com](http://www.amazingglove.com)

4. Unique Device Identification (UDI):

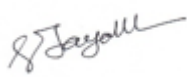
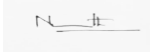

#	Product Name	Size/Variant	Basic UDI-ID
1.	The Sterile Latex Gynaecological Gloves – Powdered	5½	8908012547LGGPP5.527
		6	8908012547LGGPP6.022
		6½	8908012547LGGPP6.52C
		7	8908012547LGGPP7.027
		7½,	8908012547LGGPP7.52H
		8	8908012547LGGPP8.02C
		8½	8908012547LGGPP8.52N
		9	8908012547LGGPP9.02H

5. Intended Use:

The Sterile Latex Gynaecological Gloves – Powdered are for use in gynaecological and obstetrical 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:

Sterile Latex Gynaecological 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 made up of Natural Rubber Latex. Our Sterile Latex Gynaecological 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 Sterile Latex Gynaecological Gloves – Powdered

Name	Function	Signature	Date
Prepared By	Jayabarathi. S		25.11.2023
Reviewed By	Neethu Joseph		25.11.2023
Approved By	Georgekutty Manuel		25.11.2023

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are sterilized by gaseous method with Ethylene Oxide gas. The Sterile Latex Gynaecological Gloves – Powdered are packed in a sterility maintenance package to ensure the shelf life of 5 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 <sub>2</sub> )	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 <sub>3</sub> )	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.

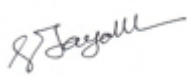


#### 10. Storage Condition

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

#### 11. Duration of use

Duration of use is transient (<60 minutes).

#### 12. Precautions & Warnings:

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Reviewed By	Neethu Joseph	Post-production		25.11.2023
Approved By	Georgekutty Manuel	Managing Director		25.11.2023

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- Do not Re Use - Reuse can cause Contamination which can lead to serious infections
- Do not Re-sterilize- Re-sterilization can cause product damage / Contamination.
- After donning remove powder by wiping gloves thoroughly with wet sterile cloth/sponge or other effective method.
- Make sure the powder does not contaminate the sterile working area
- Use micro roughened glove for added instrument grip

### 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:

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.

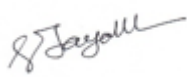


### 16. Patient Population

It can be used in pregnant, non-pregnant and breast-feeding woman for gynaecological purpose except in those 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.
- 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 high tensile strength.
- Have good fit and comfort.

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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 Gynaecological Gloves – Powdered is supplied as sterile product and the sterilization type is Ethylene oxide.

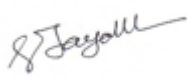
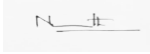

21. Disposal instructions:

- 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.

23. Explanation of symbols used on label

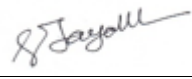
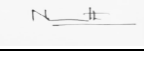

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 Do not Re-sterilize	 Do not use if package is Damaged	 Instructions for Use	 Sterilized using Ethylene Oxide	 Do not Re Use	 Storage Conditions
 Latex	 Caution	 Keep Away from Sunlight	 Keep Dry	 Lot / Batch No.	 Date of Manufacture
 Use by Date	 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 Kakkannad, Cochin-682 037, Kerala, India @infoamazingglove.com, www.amazingglove.com		 EAR Address	Europecert, Alsstr 97, 41063 Monchengladbach, Germany Email: <a href="mailto:support@europecert.eu">support@europecert.eu</a> 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 Surgical TR comments	25/03/2022
02	Updated section 7 as per Surgical TR2 comments	19/08/2022
03	Device constituent or material is updated in section 7. Duration of use is updated in section 11. Clinical benefit is updated in section 17 of IFU (ARP/LGG-PD/IFU).	25/11/2023

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