



Sterile Latex Surgical Gloves Pre-Powdered/Powdered Product Catalogue

Abstract

Catalogue describes about the company
and its products in latex gloves
manufacturing



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ABOUT COMPANY

Vijayalakshmi Health & Surgicals (VLHS) Pvt Ltd is one of the India's leading manufacturers of good quality Latex Surgical gloves and Latex Examination gloves to protect health care professionals, workers, and patients. VLHS gives priority to keep your patients and surgical staff safe from cross contamination, infection, and allergic reaction. Company's undeterred commitment to provide the best quality products and services to customers by maintaining ASTM, BIS, ISO and EN standards enabled us to become pioneer in Glove manufacturing.

Ours State-of-the-art facility is equipped by latest fully automated double former machinery and globally recognized operations standards. VLHS is standing upon a strong infrastructural base, continually striving for improvements, innovations to set new standards in Healthcare Industry and serve customers beyond expectations.

PRODUCT DESCRIPTION

Surgical Gloves manufactures by VLHS are well designed for surgeons featuring the outstanding fit, comfort, dexterity, flexibility, and protection.

The sterile Pre-Powder 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, micro rough textured in the palm area, highly elastic and tear resistant. Product is classified under Medical device Class IIa (EU MDR 2017/745), Indian Medical device (IMDR 2017) Class B and Personal protective equipment category III (EU PPE 2016/425).



UDI-DI Code: 890615299LSG-PP-E9K

REF No	Size	Pack qty
101	6	50 pairs/box
102	6.5	50 pairs/box
103	7	50 pairs/box
104	7.5	50 pairs/box
105	8	50 pairs/box
106	8.5	50 pairs/box
107	9	50 pairs/box

APPLICATION / 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.

DEVICE DETAILS

PRODUCT NAME:	Sterile Latex Surgical Gloves
BRAND/PROPRIETARY NAME:	DR.GLOVE
MODEL/VARIANTS:	Pre - Powdered / Powdered
EMDN CODE:	T01010101 - Surgical Gloves, Latex, Pre-Powdered
MDA/MDN CODE:	MDN 1214
MDS & MDT CODE(S):	MDS1005 & MDT 2004, 2011

PRODUCT SPECIFICATIONS

MATERIAL	Natural High Grade Rubber Latex
TYPE	Latex Surgical Gloves, Powdered with US FDA approved USP Grade Bio-Absorbable Corn Starch
DESIGN & FEATURES	Hand specific, curved fingers, beaded cuff
COLOUR	White
STORAGE	The gloves shall maintain their properties when stored in a dry condition at temperature not higher than 30°C. Avoid direct sunlight
STERILIZATION	Yes (EO sterilization)
SHELF LIFE	3 years from date of manufacturing
PACKING	<ul style="list-style-type: none">• One pair in paper wallet and one wallet per pouch• 50 pouches in dispenser box• 8 boxes in one carton / As per customer requirement
APPLICATION	General Surgery

KEY FUNCTIONAL BENEFITS

- Extra strength provides additional protection and strong tears resistance.
- Curved fingers reduce hand fatigue while the beaded cuffs prevent roll-back and make gloves easy to put on.
- Low powder content that minimizes skin irritation and helps in easy donning & doffing.
- Their anatomical shape, elasticity and softness provide superior fit, comfort, dexterity & flexibility.

PHYSICAL DIMENSIONS

	Size	DR.GLOVE	ASTM D 3577 / IS 13422	EN 445
LENGTH (MM)		Min 280	Min 265	Min 280
WIDTH (MM)	6	76 ± 3	76 ± 6	77 ± 5
	6.5	83 ± 3	83 ± 6	83 ± 5
	7	89 ± 3	89 ± 6	89 ± 5
	7.5	95 ± 3	95 ± 6	95 ± 5
	8	102 ± 3	102 ± 6	102 ± 6
	8.5	108 ± 3	108 ± 6	108 ± 6
	9	114 ± 3	114 ± 6	114 ± 6
THICKNESS (MM)	Finger	0.18 ± 0.02	0.10 Min	0.10 Min
	Palm	0.16 ± 0.02	0.10 Min	0.10 Min
	Cuff	0.12 ± 0.02	0.10 Min	0.10 Min

PHYSICAL PROPERTIES

		DR.GLOVE	ASTM D 3577 / IS 13422	EN 455
Tensile Strength (MPa)	BEFORE AGEING	Min 24	Min 24.0	9 N
Elongation At Break (%)		Min 800	Min 750	N/A
Tensile Strength (MPa)	AFTER AGEING	Min 20	Min 18.0	9 N
Elongation At Break (%)		Min 750	Min 560	N/A
Water Tightness Test G-1		AQL 0.65/1.5	AQL 0.65/1.5	AQL 0.65/1.5
Protein Content		< 200 µg/dm ²	< 200 µg/dm ²	< 200 µg/dm ²
Powder Content		< 15 mg/dm ²	< 15 mg/dm ²	Min 2 mg

QUALITY STANDARDS

- EN 455-1, EN 455-2, EN 455-3, & EN 455-4
- IS 13422, ASTM D 3577, & ISO 10282
- EN ISO 374 Parts 1,2,4 & 5, EN 16523, EN ISO 21420, EN ISO 15223-1, EN ISO 11135, EN ISO 11137-1, EN ISO 11737-1 & 2, EN ISO 11138-2
- CE Mark - MDR 2017/745 Class IIa Device.
- Indian Medical Device Regulation (IMDR) 2017 - Class B Device.
- Personal Protective Equipment (PPE 2016/425) - Class III device (Module D)
- Manufactured under EN ISO 13485:2016 quality management system.
- Using US FDA approved absorbable USP Grade modified corn starch.
- Bio burden and sterility tested.
- Manufactured in a clean controlled environment Room.

QUALITY CONTROL

- 100% Inspected
- Factory Standard of 0.65/1.5 AQL for Pinholes or as per the customer requirements.

PRODUCT SAFETY CONFIRMANCE

BIOCOMPATIBILITY TESTED

Pass

Test for Skin Irritation, Skin Sensitization, Toxicity, Acute systemic Toxicity and Pyrogen

STERILITY TESTED

Pass

To check the presence of bacterial in gloves after sterilization process

CHEMICAL RESIDUE TESTED

Pass

To ensure the gloves are free from any chemical substances and safe to use

BIOBURDEN TESTED

Pass

To test the numbers of bacterial living on the glove's surface that has not been sterilized

BACTERIAL ENDOTOXIN TESTED

Pass

To check the presence of bacterial in gloves
