

PROJECT PROFILE
ON
LATEX GLOVES

MONTH & YEAR
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LATEX GLOVES

INTRODUCTION

Surgical gloves and examination gloves are called Medical gloves. These gloves are medical safety accessories that ensure sanitary hospital conditions by limiting patients' exposure to infectious matter. They also serve to protect health professionals from disease through contact with body fluids.

Medical gloves are traditionally made of latex and powdered with cornstarch. Since cornstarch can impede healing if it gets into tissues (as during surgery), non-powdered gloves are being increasingly used during surgery and other sensitive procedures. Special manufacturing processes are used to compensate for the lack of powder.

There are two main types of gloves: examination and surgical. Surgical gloves have more precise sizing (numbered sizing generally from 2.5 to size 9) and may be made to higher specifications.

Due to the increasing rate of latex allergy among health professionals as well as in the general population, there has been an increasing move to gloves made of non-latex materials such as vinyl or nitrile rubber. However, these gloves have not yet replaced latex gloves in surgical procedures, as gloves made of alternate materials generally do not fully match the fine control or greater sensitivity to touch available with latex surgical gloves. High-grade non-latex gloves (such as nitrile gloves) also cost two or more times the price of their latex counterparts, a fact that has often prevents switching to these alternate materials in cost-sensitive environments, such as many hospitals.

Powder-free medical gloves are also used in medical clean room environments, where the need for cleanliness is often similar to that in a sensitive medical environment. Similar but specially tested gloves are used in electronics cleanrooms.

SPECIFICATIONS

The Latex surgical Gloves are available with the following specifications:

- They are manufactured from Natural Rubber Latex
- They are available in powdered form and powder-free form
- They have beaded cuff with minimum length of 280 mm for extra protection
- Latex gloves undergo special leaching process which removes up to 95% of common latex allergens.
- They are made powder-free and ultra-low in chemicals to reduce irritant and allergen contact dermatitis.
- They have textured palm and fingers for uncompromising wet/dry grip control.
- They are soft and supple and have comforting fit.
- They are available in five sizes namely extra small, small, medium ,large & extra large.
- They meet the Test results specification of Bureau of Indian Standards IS 13422 and IS 4148 , ASTM 3578 & EN 455 1&2 ,BS 4005
- Necessary testing of gloves is done to prevent pinholes, thick/thin spots, tear, discolouration, cuff bead, pleats, tackiness and foreign material contamination.
- General Packing methods:
- Packing sterile - One pair/piece in a pouch, 50 pouches per box, 250,000/330,000 pouches in a 20 feet container.

- Packing Non-sterile - 100 pieces in a polythene bag packed in dispenser box, 10 dispensers packed in a Master carton, 1,100,000 pieces in a 20 feet container.

Physical Dimensions							
Size	6	6.5	7	7.5	8	8.5	9
Cuff Length	280 mm (minimum)						
Palm Width	77 ± 5 mm	83 ± 5 mm	89± 5 mm	95± 5 mm	102± 6mm	108± 6mm	114± 6mm
Thickness	0.13 mm (minimum)						
Physical Properties							
	Before Ageing (Min)			After Ageing (Min)			
Tensile Strength	24Mpa/12N			18 Mpa/9N			
Elongation at Break	750% Min.			560% Min.			

Packing		
I	Sterile Gloves Unit Inner Box Master carton 20 ft. container	One pair to peel pouch/tear pouch 50 Pairs / 25 pairs 300 pairs/500 pairs 1,75,200 pairs / 2,10,000 pairs
II	Non Sterile Gloves Unit Inner Box Master carton 20 ft. container	One pair in polythene sleeve 25 pairs 500 pairs 2,75,000 pairs

MARKET POTENTIAL

The current world usage of Latex gloves is about 120 million pieces. The demand is growing at an average of 10 per cent per year. Malaysia is the largest producer/exporter of rubber glove in the world with more than 50% market share. Of the annual worldwide total production of 120 billion rubber gloves, Malaysia contributes about 60%, Thailand 30% and Indonesia 10%. Despite the stiff competition from other NR latex producers, Malaysia is still strong in this industry. The Malaysian glove industry has a production capacity of 60 billion pieces per annum. The demand of this sector is expected to grow more than 10% per annum within the next 20 years. India's share in the global exports is very negligible. Indian latex surgical gloves are mainly consumed in the domestic market.

The main manufacturers of Latex surgical gloves in the Indian market are the following.

1. Primus Glove Pvt. Ltd., Kochi.
2. Kanam latex industries Pvt. Ltd., Kochi
3. Joyco Safety Products Pvt. Ltd., Mumbai
4. Age Industries Pvt. Ltd., Palakkad
5. MRK Health care, Byculla
6. Kurian Abraham, Nagercoil
7. Shilpa Latex, Bangalore
8. Setu Shree enterprises, Pune
9. Janco Dipped Products, Pvt. Ltd., Cochin
10. Premier Surgical Products, New Delhi
11. Shree Balaji Industries, Dwaraka
12. Veecare INC, New Delhi
13. Med Surge India Pvt. Ltd., Chennai
14. Sage Shield India Rubber Products Pvt. Ltd., Cochin

There are about 200 latex gloves manufacturers in India in small and medium scale sectors.

The demand for surgical gloves is influenced by several related factors. As the surgical gloves are consumed by surgeons during surgeries, the demand is influenced by the following factors: -

- ✓ Prevalence of diseases requiring surgery
- ✓ Development in health care, hospital facilities and operation theatres.
- ✓ Medical education and growth of surgeons in society.

The demand goes up when medical facilities, number of surgeons and surgeries taken place show improvement. There is a heavy backlog of several diseases to be treated , especially those which require surgical corrections to the needy population in Indian society which could not be done so far due to:-

- ✓ Lack of medical facilities including operation theatres
- ✓ Non-affordability by the poor patients
- ✓ Insufficient number of doctors(surgeons)

As and when these facilities improve, slowly the number of surgeries will increase further better health will prevail.

Intensive immunization programmes have made good progress against diseases such as polio. Despite continuing problems, life expectancy in India has risen over the past two decades. Due to this India is now entering into its “epidemiological transition” a change in disease pattern from infections to chronic/ degenerative, due to improved child nutrition, immunization, and improved access to primary health care.

Despite having shown remarkable development in various fields, India’s health condition remains abysmally at a low level

In contrast to the strides made in water supply, sanitation has stubbornly lagged behind. Of the 3000 cities in India with more than 1, 00,000 people, only 200 have basic sewage treatment facilities. Rural sanitation remains almost

non-existent and barely one half of urban population had access to adequate sanitation according to WHO.

Considering all these aspects the demand for the essential accessory in medical healthcare such as surgical gloves is always on the increase.

INSTALLED CAPACITY

The proposed installed capacity of the unit is 4200 pairs of gloves per hour. On this basis for 300 working days on three shift basis the annual capacity works out to 30.24 million pairs gloves.

PLANT AND MACHINERY

The plant and machinery items required for the manufacturing of the latex surgical gloves consists of the following.

1. Dimension of the complete plant (l 39m * w 2m * h 4m)
2. Capacity: approximately 3,500 - 4,500 pairs of examination glove per hr at transport speed of about 7 meters per min.
3. Chains standard conveying chain of approximately total length of 150 meters, tensile strength not less than 1000kg, is driven by 5.5 horse-power variable-speed motor.
4. Formers: approximately 1400 porcelain formers per line.
5. Former washing trough: consisting of 2 single-layer rectangular stainless steel tank
6. Former dryer: heated oven dryer in rock wool insulated enclosure.
7. Coagulant drying tank: single-layer rectangular circulation tank of pt 304 stainless steel construction. false bottom with a 3 phase 1/2 horse-power gear-box drives a propeller for circulation.
8. Coagulant drying oven rock wool insulated enclosure.
9. Latex drying oven rock wool insulated enclosure

10. Latex dip tank: double-jacketed rectangular circulation tank of pt 304 stainless steel construction false bottom with a 3 phase 1/2 horse-power gear-box drives a propeller for circulation.
11. Leaching trough 1 unit of single-layer rectangular tank of pt 304 stainless steel construction
12. Beading section: complete adjustable up/down, in/out and angle approach rotation sponge beading roller complete with formers spinning accelerator, and is powered by 3 units of 3 phase 1/2 horse-power gear-box motor
13. Main oven (drying/vulcanizing) rock wool insulated vulcanizing oven
14. Electric control panel: electric control panel with built-in regulating devices and switches. push-buttons switch program protected against mistakes, chain protected against overload.
15. Other general equipments such as Boiler, Ball mill, Dryers, Testing and laboratory equipments, EO sterilization unit.

The machinery suppliers normally provide for the following services.

- Complete supply and installation of condom / gloves manufacturing plant
- Manufacturing process design includes know-how supply.
- Technology transfer
- Technical after-sales consultancy services

The main equipment suppliers are located in Malaysia and Taiwan

MANUFACTURING PROCESS

The process of manufacturing of latex Surgical gloves can be explained as follows:

Natural rubber (NR) latex is predominantly used in the production of surgical and examination gloves. This is attributed to the superior processing behaviour of natural rubber latex and high physical strength of gloves made from natural rubber latex. The production of latex gloves involves a process of coagulant

dipping, in a continuous chain dipping line. During the coagulant dipping operation, clean porcelain formers are first dipped into a coagulant solution, usually calcium nitrate and then into a natural rubber latex compound. The next stage involves the bead rolling of the gloves by rotating brushes after a short drying. This followed by leaching of the wet gel on the former in hot water. Corn-starch is then applied to the outer surface of the formers *via* a slurry dip before the gloves are subjected to a drying and vulcanisation process in an oven. Subsequently, the dried gloves are manually stripped from the porcelain formers, tested and packed.

For good quality control of the product the following points have to be taken care of.

The compounded latex has to be further clarified to remove excess chemicals if any.

The beaded gloves are Pre-Leached in 80 ft. of treated hot water to wash off non-rubber particles and rubber chemical residues that could otherwise remain on the glove and can cause allergic contact dermatitis. The water used in the leaching tanks are treated to prevent bacterial contamination and heated to improve leaching efficiency. The system includes four Pre-Leach tanks of hot flowing water, which are constantly monitored to meet required parameters.

The gloves are properly Vulcanized to ensure best physical properties and to reduce moisture content. It is Post-Leached again in 60 ft. of hot flowing water at 70-80°C. This washes off much of the extractable Water Soluble Latex Protein, Residual Chemicals and other non-rubber particles

Only imported, U.S. FDA approved Bio-Absorbable Dusting Powder USP is used to powder the gloves. The powder in the tanks are closely monitored and controlled for bacteria build up and protein content. The powder content on the glove is monitored to keep within levels as per standards of ASTM D-3577

To reduce powder content in gloves to less than 15 $\mu\text{g}/\text{dm}^2$ and reduce moisture level to less than 0.75%, the gloves are Tumbled in a validated process cycle with temperature and time critically controlled.

High powder content and moisture can result in Microbial Growth, causing discoloration and unpleasant odour.

The Powder Free Gloves are processed in a special, separate area. To produce Powder Free Gloves, the Pre-Powdered Gloves are Washed, Chlorinated, Neutralized, Rinsed and Dried. The extractable latex protein content of these gloves is less than 50 $\mu\text{g}/\text{dm}^2$.

In addition to Watertight Test, each batch of glove is electronically tested for micro pores. Even though the controlled production produces gloves with less than 1% pinholes, 100% inspection is being done. The normal tests such as standard airtight test and Watertight test are conducted. The glove is electronically tested for micro pores. This kind of electronic testing detects micro pores that otherwise might not be detectable during watertight and airtight test.

The well equipped laboratory with all the facilities and equipment to test quality of raw materials, physical properties of gloves and protein content of gloves using a Spectrophotometer has to be set up. Estimation of protein is done for every batch of gloves, as per ASTM – D5712 using Modified Lowry Method.

The inhouse Microbiological Laboratory also monitors Bio-Burden Level and Sterility. The laboratory has to be equipped with Laminar air flow cabinet and is manned by trained and skilled microbiologists.

Packing Section should be clean and dust free with positive pressure filtered air system with controlled exit and entry points. It should be kept clean and fumigated at regular intervals to ensure low bio-burden level.

State-of-the-art Packing Machines have to be installed for Walletting, Pouching and Sealing the gloves automatically thereby reducing human contact with the gloves to a minimum. The Walletting Machines prints and folds the wallets in-house thereby reduces contamination.

The Pouching Machine is specially designed for automatic packing of gloves. It incorporates skip sealing, photo electric cell for registration as well as a flexography system for printing of batch and other manufacturing details.

Moreover, the Pouching Machines ensure an aesthetic packing system and the integrity of the pouches. The entire process is done in a controlled and clean environment. There will be very little chance of contamination and maintaining a greater degree of hygiene. The packed gloves are once again quality assurance checked and passed for sterilization.

State-of-the-art P.L.C controlled E. T. O. Sterilization Plants with a double door system are installed which is validated to EN 550 Norms. Each process cycle's efficiency is monitored with Bio-Monitors. The process cycle also includes sufficient Air Wash Cycle to ensure that residual E. O. on the glove is low.

The carefully selected packing material used ensures that it is suitable to permit E. O. sterilization and maintain sterility during transit and storage for the shelf life of the product.

The sterilized gloves are tested for sterility in the in-house Micro Biological Laboratory.

The finished goods are cleared by Quality Control Department and Quality Assurance and undergoes Consignment Audit which includes

- Correctness of quality, type and sizes as per order
- Correctness in pairing
- Correctness of stamping particulars
- Correctness of packing materials
- Correctness of marking on pouch / box
- Conformance to specifications of the relevant grade of gloves
- Compliance to all previous inspection and test requirements
- Only the gloves which pass the specifications are transferred to the warehouse for shipment

RAW MATERIALS

The main raw materials required for the manufacture of latex Surgical gloves are the following:

Particulars	Wet	Dry
60% Centrifuged latex	167	100
20% Potassium hydroxide solution	5	0.5
50% Sulphur dispersion	2	0.3
50% Pilcure ZDC dispersion	1	0.2
50% Pilcure ZDBC dispersion	1	0.25
50% Zinc oxide dispersion	1	1
50% Pilnox 22 M 46 dispersion*	2	1
Total	179	

Natural latex is produced from the *Hevea brasiliensis* rubber tree and is the protective fluid contained beneath the bark. It is a cloudy white liquid, similar in appearance to cow milk. It is collected by cutting a thin strip of bark from

the tree and allowing the latex to exude into a collecting vessel over a period of hours.

The composition of latex sap consists of 30-40% rubber particles, 55-65% water, and small amounts of protein, sterol glycosides, resins, ash, and sugars. Rubber has high elasticity and a polymer molecular structure. This structure consists of a long chain made up of tens of thousands of smaller units, called monomers, strung together. Each monomer unit has a molecular size comparable with that of a simple substance such as sugar. Other special chemicals are used as preservatives or stimulants during the harvesting process.

Both synthetic and natural rubber production require the use of vulcanizing chemicals, primarily sulfur. Oil is often used to help processing and reduce cost.

The materials are available from import sources mainly from Malaysia.

The various additives and chemicals are available from the reputed suppliers of chemicals namely, Bayer India, NOCIL, ICI ltd etc. They have selling offices in Chennai.

For -Nos of pairs	30240000		
	Qty-kgs	Rate/kg	Value
	for pairs		Rs
1 Tonne of FG	25000	Pairs	
60% Centrifuged latex	933	150.00	139944.13
20%Potassium Hydroxide-stabiliser	28	100.00	2793.30
Sulphur dispersion-50%	11	15.00	167.60
50% Pilicure ZDC dispersion	6	200.00	1117.32

50% PilcureZDBC dispersion	6	270.00	1508.38
50% Zinc oxide dispersion	6	100.00	558.66
50% Pilnx 22M46 dispersion	11	195.00	2178.77
			148268.16
Raw material cost per pair-Rs			5.93
Total raw material cost		Rs. lakhs	1793.45
Packing materials	30240000	0.40	120.96

LOCATION, LAND AND BUILDING

An area of 2 acres will be sufficient for the factory. The constructed building area requirement will be about 15000 sq.ft.

UTILITIES

POWER: The total requirement of power for the plant is about 250 HP.

Water: The water requirement of the unit is 200000 litres of treated water per day including the requirements for processing, boiler, and human consumption. About 80% of the water can be recycled.

Transport: The raw materials can be transported from the Port by engaging private lorries.

Manpower:

The manpower requirement of the unit is estimated as given below

Designations	Nos
Factory manager	1

Supervisor	9
Lab technician	3
Skilled	108
Unskilled	9
Marketing Manager	1
Representatives	5
Accountant	1
Accounts Assistant	3
Security	3

SCHEDULE OF IMPLEMENTATION

After making the financing arrangements of the unit and after the construction of the building, the project implementation will take about three months time

ASSUMPTIONS

Installed capacity	302.40 lakhs pairs Latex Surgical Gloves per annum (30.24 million pairs)
Capacity utilisation	Year-1-60% Year-2-70% Year-3-80%
Selling price	Rs.8.50 per pair- sales value Rs.1360.80 lakhs at 100% capacity utilisation
Raw material cost	As per details given above
Consumables	As per details given above
Power & fuel	Rs.102.60 lakhs at 100% capacity utilisation
Wages and salaries	Rs.113.33 lakhs per annum
Repairs and maintenance	Rs.12.00 lakhs per annum

Depreciation	10% on building and 15% on machinery
Selling General and administrative expenses	Rs.24.00 lakhs per annum
Interest on Term loan	14% per annum
Interest on working capital	14% per annum
Income tax	34% on taxable income

LIST OF MACHINERY SUPPLIERS

1. WARISAN TEGAS SDN BHD, 41A, JALAN 21/12, SEA PARK, 46300 PETALING JAYA, SELANGOR DARUL EHSAN. MALAYSIA TEL : (60)-3-78768527 (Hunting Line), FAX : (60)-3-78753067, EMAIL : sales@warisantegas.com,

2. Hand Best International Co Ltd, No. 365, Min Shen St., Hsiu Shui Hsiang, Chang Hua Hsien 50446, Taiwan, Tel: 886-4-7689906, FAX: 886-4-7689905
E-mail: asian.success@msa.hinet.net, E-mail: asgloves@ms66.hinet.net,
Http: www.glovemachine.com.tw

3. Richter Rubber Technology, Factory: Plot 33, Kuala Ketil Industrial State, 09300 Kedah, Malaysia, Tel: 60 4 416 1668 / 9 Fax: 60 4 416 1667 ; Email: richter@RichterRubber.com ["60" is the International Country Code for Malaysia, while the first "4" shown is the City Code]

4. Mr.John Woon, Latex gloves and consultant, E-Mail: woonsungliang@yahoo.com.sg, Malaysia,

- 5.Fable Crest Sdn Bhd
41A Jalan 21 / 12 Sea Park

Petaling Jaya
Selangor Darul Ehsan
Malaysia
46300
Phone: 50-3-78793770

6.S&F Inc
2nd Floor Venture Town B / D, 447-1 Manduk1-Dong Buk-Gu
Busan
South Korea -616111
Phone-82-51-3351110
www.snfinc.net

7. Canton Glove Manufacturing Co Ltd

Nanyang Village Donghu Avenue Xinhua Street,HuaduDistrict of Guangzhou
City

Guangzhou City
China (Mainland) 510800
Phone:86-020-36917226,18928930353

RAW MATERIALS

Variuos Latex dealers and suppliers in Kottayam, India and Malayasia.

Can be obtained from Rubber Board website

FINANCIAL ASPECTS

1. COST OF PROJECT

[Rs.lakhs]

Land	30.00
Building	120.00
Plant & Machinery	300.00

Other Misc. assets	5.00
Pre-Operative expenses	20.00
Margin for WC	76.65

Total	551.65
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2. MEANS OF FINANCE

Capital	213.65
Term Loan	338.00

Total	551.65
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3. COST OF PRODUCTION & PROFITABILITY STATEMENT

[Rs.lakhs]

Years	1	2	3	4	5
Installed Capacity-No of Pairs	30240000	30240000	30240000	30240000	30240000
Utilisation	60%	70%	80%	80%	80%
Production/Sales-No of pairs	18144000	21168000	24192000	24192000	24192000
Selling Price per pair -Rs.	8.50				

Sales Value (Rs.lakhs)	1542.24	1799.28	2056.32	2056.32	2056.32
Raw Materials	1076.07	1255.42	1434.76	1434.76	1434.76
Packing Materials	72.58	84.67	96.77	96.77	96.77
Power& fuel	61.56	71.82	82.08	82.08	82.08
Wages & Salaries	113.33	118.99	124.94	131.19	137.75
Repairs & Maintenance	12.00	13.20	14.52	15.97	17.57
Depreciation	60.50	52.05	44.81	38.59	33.26
Cost of Production	1396.04	1596.15	1797.88	1799.36	1802.19
Selling, Admin, & General exp	24.00	25.20	26.46	27.78	29.17
Interest on Term Loan	47.32	41.41	29.58	17.75	5.92
Interest on Working Capital	33.32	33.32	33.32	33.32	33.32
Total	1500.68	1696.08	1887.24	1878.21	1870.60
Profit Before Tax	41.56	103.20	169.09	178.11	185.72
Provision for tax	14.13	35.09	57.49	60.56	63.15
Profit After Tax	27.43	68.11	111.60	117.55	122.57
Add: Depreciation	60.50	52.05	44.81	38.59	33.26
Cash Accruals	87.93	120.16	156.40	156.14	155.83
Repayment of Term loan	0.00	84.50	84.50	84.50	84.50

4. WORKING CAPITAL:

Months Consumptions	Values	%	Margin Amount	Bank Finance
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Raw Materials	2.00	179.35	25%	44.84	134.51
Consumables	2.00	12.10	25%	3.03	9.07
Finished goods	0.50	58.17	25%	14.54	43.63
Debtors	1.00	128.52	10%	12.85	115.67
Expenses	1.00	1.39	100%	1.39	0.00
		379.53		76.65	302.88

5. PROFITABILITY RATIOS BASED ON 80% UTILISATION

<u>Profit after Tax</u>	=	<u>111.60</u>	5%
Sales		2056.32	

<u>Profit before Interest and Tax</u>	=	<u>231.99</u>	27%
Total Investment		854.53	

<u>Profit after Tax</u>	=	<u>111.60</u>	52%
Promoters Capital		213.65	

6. BREAK EVEN LEVEL

Fixed Cost (FC):

[Rs.lakhs]

Wages & Salaries	124.94
Repairs & Maintenance	14.52
Depreciation	44.81
Admin. & General expenses	26.46
Interest on TL	29.58
	<hr/>
	240.31
	<hr/>
Profit Before Tax (P)	169.09

$$\text{BEL} = \frac{\text{FC} \times 100}{\text{FC} + \text{P}} = \frac{240.31}{409.39} \times \frac{80}{100} \times 100$$

47% of installed capacity

