STERILE LATEX SURGICAL GLOVES POWDERED

1. **REFERENCE :** Test proceed according to EN 455-1,2,3 and ASTM D 3577, ASTM F 1671

2. **BRAND : PRISTEEN, PRISTEEN++, PERFEKTO, PROTEZIONE, HOSPICARE**

3. **MANUFACTURED BY: Beta Healthcare Products Pvt.Ltd.**
   Plot No.21B, Cochin Special Economic Zone,
   KakkanadKochi-682 037, Kerala, India

4. **PRODUCT DESCRIPTION:**
   - Gloves compounded primarily from natural rubber latex (Type-1).
   - Creamy white to pale yellow in colour (Natural colour).
   - Free from dirt marks, oil stains, embedded foreign particles, coagulum etc.
   - EO Sterilized.
   - Gamma sterilized (as per customer requirement).

5. **PRODUCT DESIGN& FEATURES:**
   - Anatomically shaped with the thumb positioned towards the palmer surface of the Index finger ratherthan laying flat.
   - Lightly powdered with modified absorbable Corn Starch USP grade.
   - The inside and outside of the latex surgical gloves shall be free of talc.
   - The cuff shall fit closely without being constrictive and it shall not roll back or ruck whilst in use.
   - Micro rough surface in palm and finger area.
   - Shelf-life is 5 years.
   - The Sterility Assurance Level (SAL) is 10^{-6}.
   - Biologically compatible as per ISO 10993-Part 5 &10
   - Conforms to ASTM 1671

6. **INTDENDED USE:**
   - Gloves intended for use in surgical work and to be worn once and then discarded. The glove is worn onthe hand of surgeon and healthcare personnel to prevent cross-contamination between healthcare personnel and patient's body, fluids, waste or environment. The gloves are designed for transient use and are intended to be used in conjunction with invasive surgery.

7. **GENERAL INSTRUCTIONS:**
   - Store the gloves in cool, dry place and away from direct sun light.
   - Sterile Gloves for single use only. Sterile until package is opened or damaged.
   - This product contains natural rubber latex which may cause allergic reactions including anaphylacticresponses in some individuals.
   - After donning remove powder by wiping gloves thoroughly with a sterile wet sponge, sterile wet towelor other effective method.
   - Reuse of gloves may cause infection, allergic reaction and poor barrier protection.

8. SPECIFICATION

PHYSICAL DIMENSION

- Reference Standard: EN 455-2:2015
- Sampling Plan: Sample Size 13 pcs, all shall comply

LENGTH AND WIDTH: For all sizes

Size	Length (mm)		Palm Width (mm)	
	Length as per EN 455-2:2015	Beta Specification	Palm width as per EN 455-2:2015	Beta Specification
5 ½	250	280mm	72±4	72-75
6	260	280mm	77±5	77-78
6 ½	260	280mm	83±5	83-84
7	270	280mm	89±5	89-90
7 ½	270	280mm	95±5	95-96
8	270	280mm	102±6	101-102
8 ½	280	280mm	108±6	107-108
9	280	280mm	114±6	113-114

THICKNESS: For all sizes

Thickness		
Locations	**Specification as per ASTM D 3577**	**Beta**
Finger	0.1 mm	Min 0.18 mm
Palm	0.1 mm	Min 0.16 mm
Cuff	0.1 mm	Min 0.12 mm

WEIGHT: For all sizes

Size	Weight per pair(Gram)
5 ½	13.2 – 13.7
6	14.0 – 14.5
6 ½	15.0 – 15.5
7	16.0 – 16.5
7 ½	18.0 – 18.5
8	19.0 – 19.5
8 ½	21.0 – 21.5
9	23.0 – 23.5

PHYSICAL PROPERTIES:

- Reference Standard: EN 455-2:2015
- Sampling Plan: Sample Size 13 pcs, all shall comply

Force at break

Characteristics	Specification	
	Before Ageing	**After Ageing 70 ± 2 C for 168 hrs.**
Force at Break (N) minimum	9	9

Tensile Strength and Elongation percentage as per ASTM D 3577

Characteristics	Specification	
	Before Ageing	**After Ageing 70 ± 2 C for 168 hrs.**
Tensile strength/Min Elongation percentage	24MPa/min 750%	Min.18 MPa/min 560%

Powder Content

- Reference Standard: EN 455-3:2015
- Specification: ≤15 mg / dm^2

Protein Content

- Reference Standard: EN 455-3:2015
- Specification: ≤ 50 ug/dm^2

Holes

- Reference Standard: EN 455-1:2020
- Sampling Plan: G1 AQL 0.65

Sterility

- Reference Standard: EN ISO 11737-2:2020
- Sampling Plan: No sterility failure

Seal strength (primary pack or pouch)

- Reference Standard: EN 868-5
- Specification: ≥ 1.2N/15mm

Type of opening of the pouch- Peel open

9. LABELING: As per regulatory requirement/Approved artworks

- Wallet
- Pouch
- Inner Carton
- Outer Carton

10. PACKAGING:

Sl.No.	Packaging	Contents
1	Wallet Paper	1 pair of gloves
2	Pouch	1 pair of gloves
3	Inner Carton	50 pouches
4	Outer Carton	8 dispenser carton box

11. Marking of the individual pouches, inner carton box, outer carton box	LOT : Mfg. Date : Expiry Date : Sterilization Date:

Prepared By: **Approved By:**

Chemist **General Manager**

STERILE LATEX SURGICAL GLOVES POWDER FREE

1. **REFERENCE :** Test proceed according to EN 455-1,2,3 and ASTM D 3577, ASTM F 1671

2. **BRAND : PRISTEEN, PRISTEEN++, PERFEKTO, PROTEZIONE, HOSPICARE**

3. **MANUFACTURED BY: Beta Healthcare Products Pvt. Ltd.**
   Plot No.21B, Cochin Special Economic Zone,
   KakkanadKochi-682 037, Kerala, India

4. **PRODUCT DESCRIPTION:**
   - Gloves compounded primarily from natural rubber latex (Type-1).
   - Creamy white to pale yellow in colour (Natural colour).
   - Free from dirt marks, oil stains, embedded foreign particles, coagulum etc.
   - EO Sterilized.
   - Gamma sterilized (as per customer requirement).

5. **PRODUCT DESIGN& FEATURES:**
   - Anatomically shaped with the thumb positioned towards the palmer surface of the Index finger ratherthan laying flat.
   - Polymer gloves coated with unique blend of polymer to provide excellent donning capability
   - The inside and outside of the latex surgical gloves free from powder.
   - The cuff shall fit closely without being constrictive and it shall not roll back or ruck whilst in use.
   - Micro rough surface in palm and finger area.
   - Shelf-life is 5 years.
   - The Sterility Assurance Level (SAL) is 10^{-6}.
   - Biologically compatible as per ISO 10993-Part 5 &10
   - Conforms to ASTM 1671

6. **INTDENDED USE:**
   - Gloves intended for use in surgical work and to be worn once and then discarded. The glove is worn onthe hand of surgeon and healthcare personnel to prevent cross-contamination between healthcare personnel and patient's body, fluids, waste or environment. The gloves are designed for transient use and are intended to be used in conjunction with invasive surgery.

7. **GENERAL INSTRUCTIONS:**
   - Store the gloves in cool, dry place and away from direct sun light.
   - Sterile Gloves for single use only. Sterile until package is opened or damaged.
   - This product contains natural rubber latex which may cause allergic reactions including anaphylacticresponses in some individuals.
   - Reuse of gloves may cause infection, allergic reaction and poor barrier protection.

8. SPECIFICATION

PHYSICAL DIMENSION

- Reference Standard: EN 455-2:2015
- Sampling Plan**:** Sample Size 13 pcs, all shall comply

LENGTH AND WIDTH: For all sizes

Size	Length (mm)		Palm Width (mm)	
	Length as per EN 455-2:2015	Beta Specification	Palm widthas per EN 455-2:2015	Beta Specification
5 ½	250	280	72±4	72-75
6	260	280	77±5	77-78
6 ½	260	280	83±5	83-84
7	270	280	89±5	89-90
7 ½	270	280	95±5	95-96
8	270	280	102±6	101-102
8 ½	280	280	108±6	107-108
9	280	280	114±6	113-114

THICKNESS: For all sizes

Thickness		
Locations	**Specification as per ASTM D 3577**	**Beta**
Finger	0.1 mm	Min 0.18 mm
Palm	0.1 mm	Min 0.16 mm
Cuff	0.1 mm	Min 0.12 mm

WEIGHT: For all sizes

Size	Weight per pair(Gram)
5 ½	13.2 – 13.7
6	14.0 – 14.5
6 ½	15.0 – 15.5
7	16.0 – 16.5
7 ½	18.0 – 18.5
8	19.0 – 19.5
8 ½	21.0 – 21.5
9	23.0 – 23.5

PHYSICAL PROPERTIES:

- Reference Standard: EN 455-2:2015
- Sampling Plan: Sample Size 13 pcs, all shall comply

Force at break

Characteristics	Specification	
	Before Ageing	**After Ageing 70 ±2 C for 168 hrs.**
Force at Break (N) minimum	9	9

Tensile Strength and Elongation Percentage as per ASTM D 3577

Characteristics	Specification	
	Before Ageing	**After Ageing 70 ±2 C for 168 hrs.**
Tensile strength/ Elongation percentage	Min 24MPa/min 750%	Min.18MPa/min 560%

Powder Content

- Reference Standard: EN 455-3:2015
- Specification: ≤2 mg / glove

Protein Content

- Reference Standard: EN 455-3:2015
- Specification: ≤ 50 ug/dm^2

Holes

- Reference Standard: EN 455-1:2020
- Sampling Plan: G1 AQL 0.65

Sterility

- Reference Standard: EN ISO 11737-2:2020
- Sampling Plan: No Bioburden Content

Seal strength (primary pack or pouch)

- Reference Standard: EN 868-5
- Specification: ≥ 1.2N/15mm

Type of opening of the pouch- Peel open

9. LABELING: As per regulatory requirement/Approved artworks

- Wallet
- Pouch
- Inner Carton
- Outer Carton

10 PACKAGING:

Sl.No.	Packaging	Contents
1	Wallet Paper	1 pair of gloves
2	Pouch	1 pair of gloves
3	Inner Carton	50 pouches
4	Outer Carton	8 dispenser carton box

11. Marking of the individual pouches, inner carton box, outer carton box	LOT : Mfg. Date : Expiry Date : Sterilization Date:

Prepared By: **Chemist**

Approved By: **General Manager**

NABL ACCREDITED
Certificate No. : TC-5410

TEST REPORT

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Sample ID No.	TAS/21-22/3365	**ULR No**	TC541021000001483
Sample received Date	01/11/2021	**Test Report No.**	TAS/REP/5916
Analysis start Date	02/11/2021	**Report Date**	12/11/2021
Analysis completed Date	10/11/2021	**Report type**	Original
Customer Ref No.	Your TRF dated 01/11/2021	**Total Page(s)**	1 of 1
Name of the customer	**M/s. BETA HEALTHCARE PRODUCTS PVT. LTD**		
Address	Plot No: 21B, Cochin Special Economic Zone (CSEZ), Kakkanad P.O, Cochin - 682 037, Kerala State, India.		

SAMPLE DETAILS

Name of the sample	Sterile Latex Surgical Gloves Powder Free	**Test Method/ Specification**	EN 455-1:2020, EN 455 - 2 & 3 :2015
Batch No	2109I/08, 09, 10, 11	**Size**	6.0, 6.5, 7.0, 7.5
Quantity received	232 Pairs	**Mfg. Date**	2021.09
Batch Size	214000 Pairs	**Exp. Date**	2025.08
Mfg. by	M/s. Beta Healthcare Products Pvt. Ltd, Cochin.	**Brand**	Surgilex

TEST RESULTS

S. No.	Name of the Test parameter(s)	Test Method/Clause No.	Specification Limits Min.	Specification Limits Max.	Results Obtained	Sample Status
1	**Dimension - Size : 6.0 (2109I/08)**					
	Length (mm)	EN 455-2:2015 (Clause 4.2 & 4.3)	260	--	Median : 289	Passes the test
	Width (mm)		72	82	Median : 78	Passes the test
2	**Dimension - Size : 6.5 (2109I/09)**					
	Length (mm)	EN 455-2:2015 (Clause 4.2 & 4.3)	260	--	Median : 284	Passes the test
	Width (mm)		78	88	Median : 83	Passes the test
3	**Dimension - Size : 7.0 (2109I/10)**					
	Length (mm)	EN 455-2:2015 (Clause 4.2 & 4.3)	270	--	Median : 288	Passes the test
	Width (mm)		84	94	Median : 91	Passes the test
4	**Dimension - Size : 7.5 (2109I/11)**					
	Length (mm)	EN 455-2:2015 (Clause 4.2 & 4.3)	270	--	Median : 285	Passes the test
	Width (mm)		90	100	Median : 96	Passes the test
5	**Physical Properties - Size : 7.0**					
	Force at Break (N) (Before Ageing)	EN 455-2:2015 (Clause 5.2)	9.0	--	Median : 16.2	Passes the test
	Force at Break (N) (After Ageing @70° C for 168 Hrs)	EN 455-2:2015 (Clause 5.3)	9.0	--	Median : 15.6	Passes the test
6	**Freedom from Holes** (315 pcs)@0.65 AQL -Size:7.0	EN 455-1 : 2020	05 Pcs	06 Pcs	Defects : 02	Passes the test
7	**Powder Residue** (mg/glove) - Size: 7.0	EN 455-3 : 2015	--	2.0	Average: 0.98	Passes the test

Opinion and interpretation (if any):

The submitted samples Passes as per EN 455-1:2020, EN 455- 2 & 3:2015 specifications with respect to the above tests only.

Abbreviations: EN : European Standard; mm: Milli meter; mg : milli gram; N : Newton;

....End of Report....

Reported by
12/11/2021
K.SENTHILKUMAR
TECHNICAL MANAGER

Approved by
12/11/2021
M. MAHENDRAN
QUALITY MANAGER

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* The test results in this report refer only to the sample tested in the laboratory and the sample submitted by the party. *

NABL Accredited Laboratory vide cert. No: TC-5410 valid upto 30/03/2022, CDSCO Registration No : TL/MD/2020/000002

TRUSTIN ANALYTICAL SOLUTIONS PRIVATE LIMITED
R.K Complex, First Floor, Plot No.303/B, B-Block, Thiruneermalai Road,
Parvathy Puram, Chrompet, Chennai-600 044, Tamil Nadu, India.
Ph: 044-22731006, Email : customercare@trustingroup.in, web: www.trustingroup.in

NABL ACCREDITED
Certificate No. : TC-5410

TEST REPORT

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Sample ID No.	TAS/21-22/3367	**ULR No**	TC541021000001485
Sample received Date	01/11/2021	**Test Report No.**	TAS/REP/5918
Analysis start Date	02/11/2021	**Report Date**	12/11/2021
Analysis completed Date	10/11/2021	**Report type**	Original
Customer Ref No.	Your TRF dated 01/11/2021	**Total Page(s)**	1 of 2
Name of the customer	**M/s. BETA HEALTHCARE PRODUCTS PVT. LTD**		
Address	Plot No: 21B, Cochin Special Economic Zone (CSEZ), Kakkanad P.O, Cochin - 682 037, Kerala State, India.		

SAMPLE DETAILS

Name of the sample	Sterile Latex Surgical Gloves, Powder Free	**Test Method/ Specification**	EN 455-1: 2020, EN 455 - 2 & 3:2015
Batch No	2109K/08, 09, 10, 11, 12, 13, 14	**Size**	6.0, 6.5, 7.0, 7.5, 8.0, 8.5 & 9.0
Quantity received	271 Pairs	**Mfg. Date**	2021.09
Batch Size	386000 Pairs	**Exp. Date**	2025.08
Mfg. by	M/s. Beta Healthcare Products Pvt. Ltd, Cochin.	**Brand**	Surgilex

TEST RESULTS

S. No.	Name of the Test parameter(s)	Test Method/Clause No.	Specification Limits		Results Obtained	Sample Status
			Min.	Max.		
1	**Dimension - Size : 6.0 (2109K/08)**					
	Length (mm)	EN 455-2:2015 (Clause 4.2 & 4.3)	260	--	Median : 289	Passes the test
	Width (mm)		72	82	Median : 77	Passes the test
2	**Dimension - Size : 6.5 (2109K/09)**					
	Length (mm)	EN 455-2:2015 (Clause 4.2 & 4.3)	260	--	Median : 287	Passes the test
	Width (mm)		78	88	Median : 82	Passes the test
3	**Dimension - Size : 7.0 (2109K/10)**					
	Length (mm)	EN 455-2:2015 (Clause 4.2 & 4.3)	270	--	Median : 289	Passes the test
	Width (mm)		84	94	Median : 90	Passes the test
4	**Dimension - Size : 7.5 (2109K/11)**					
	Length (mm)	EN 455-2:2015 (Clause 4.2 & 4.3)	270	--	Median : 289	Passes the test
	Width (mm)		90	100	Median : 96	Passes the test
5	**Dimension - Size : 8.0 (2109K/12)**					
	Length (mm)	EN 455-2:2015 (Clause 4.2 & 4.3)	270	--	Median : 286	Passes the test
	Width (mm)		96	108	Median : 102	Passes the test
6	**Dimension - Size : 8.5 (2109K/13)**					
	Length (mm)	EN 455-2:2015 (Clause 4.2 & 4.3)	280	--	Median : 285	Passes the test
	Width (mm)		102	114	Median : 107	Passes the test
7	**Dimension - Size : 9.0 (2109K/14)**					
	Length (mm)	EN 455-2:2015 (Clause 4.2 & 4.3)	280	--	Median : 288	Passes the test
	Width (mm)		108	120	Median : 113	Passes the test

Reported by
12/11/2021
K.SENTHILKUMAR
TECHNICAL MANAGER

Approved by
12/11/2021
M. MAHENDRAN
QUALITY MANAGER

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TRUSTIN ANALYTICAL SOLUTIONS PRIVATE LIMITED
R.K Complex, First Floor, Plot No.303/B, B-Block, Thiruneermalai Road,
Parvathy Puram, Chrompet, Chennai-600 044, Tamil Nadu, India.
Ph: 044-22731006, Email : customercare@trustingroup.in, web: www.trustingroup.in

NABL ACCREDITED
Certificate No. : TC-5410

TEST REPORT

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Sample ID No.	TAS/21-22/3367	**ULR No**	TC541021000001485
Sample received Date	01/11/2021	**Test Report No.**	TAS/REP/5918
Analysis start Date	02/11/2021	**Report Date**	12/11/2021
Analysis completed Date	10/11/2021	**Report type**	Original
Customer Ref No.	Your TRF dated 01/11/2021	**Total Page(s)**	2 of 2
Name of the customer	**M/s. BETA HEALTHCARE PRODUCTS PVT. LTD**		
Address	Plot No: 21B, Cochin Special Economic Zone (CSEZ), Kakkanad P.O, Cochin - 682 037, Kerala State, India.		

SAMPLE DETAILS

Name of the sample	Sterile Latex Surgical Gloves, Powder Free	**Test Method/ Specification**	EN 455-1: 2020, EN 455 - 2 & 3:2015
Batch No	2109K/08, 09, 10, 11, 12, 13, 14	**Size**	6.0, 6.5, 7.0, 7.5, 8.0, 8.5 & 9.0
Quantity received	271 Pairs	**Mfg. Date**	2021.09
Batch Size	386000 Pairs	**Exp. Date**	2025.08
Mfg. by	M/s. Beta Healthcare Products Pvt. Ltd, Cochin.	**Brand**	Surgilex

TEST RESULTS

S. No.	Name of the Test parameter(s)	Test Method/Clause No.	Specification Limits		Results Obtained	Sample Status
			Min.	Max.		
8	**Physical Properties - Size : 7.0**					
	Force at Break (N) (Before Ageing)	EN 455-2:2015 (Clause 5.2)	9.0	--	Median : 16	Passes the test
	Force at Break (N) (After Ageing @70° C for 168 Hrs)	EN 455-2:2015 (Clause 5.3)	9.0	--	Median : 13	Passes the test
9	**Freedom from Holes** (315 pcs)@0.65 AQL -Size: 7.0	EN 455-1 : 2020	05 Pcs	06 Pcs	Defects : 0	Passes the test
10	**Powder Residue** (mg/glove) - Size: 7.0	EN 455-3 : 2015	--	2.0	Average: 1.07	Passes the test

Opinion and interpretation (if any):

The submitted samples Passes as per EN 455-1:2020, EN 455- 2 & 3:2015 specifications with respect to the above tests only.

Abbreviations: EN : European Standard; mm: Milli meter; mg : milli gram; N : Newton;

....End of Report....

Reported by

12/11/2021

K.SENTHILKUMAR
TECHNICAL MANAGER

Approved by

12/11/2021

M. MAHENDRAN
QUALITY MANAGER

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NABL Accredited Laboratory vide cert. No: TC-5410 valid upto 30/03/2022, CDSCO Registration No : TL/MD/2020/000002

1. Product Name

Sterile Latex Surgical Gloves Powder Free

2. Brand Name

Description	Powder free
Surgical Gloves –EO Sterile	Pristeen Pristeen++ Perfekto Protezione Hospicare
Surgical – Gamma	Gant d'intervention Intervention Pristeen Pristeen++

3. Name and Address of the manufacture:

Beta Healthcare Products Private. Limited.
Plot No.21B, Cochin Special Economic Zone,
Kakkanad, Kochi-682 037, Kerala, India.
Tel: +91-484 2413340, Fax: +91- 2413341
www.betahealthcare.com

4. Unique Device Identification (UDI)

Sl. No	Product Name	Size	GMN (Basic UDI-DI)	GTIN 13	Brand Name	GTIN 14
1	Surgical Gloves Powder Free	6.0	8908000843LSGPF9E	8908000843097	Pristeen	G08908000843097
2		6.5		8908000843110		G08908000843110
3		7.0		8908000843127		G08908000843127
4		7.5		8908000843134		G08908000843134
5		8.0		8908000843141		G08908000843141
6		8.5		8908000843158		G08908000843158
7		9.0		8908000843165		G08908000843165

5. Product Description

The sterile latex surgical gloves powder free are manufactured with Natural Rubber Latex. These gloves are sterilized by using gaseous method (EO Gas) or Gamma irradiation method as per customer demands.

These latex gloves carry the following features:

- Sterile
- Curved finger shaped (Hand Specific, Right or Left)
- Micro-roughened texture finish
- Beaded and long cuff gloves.
- Polymer coated for powder free gloves
- Single Use
- Gloves specifications are as per EN 455-1, 2, 3, 4 / ASTM D 3577 standards.
- Anatomical shape

These gloves are supplied as a pair and packed and identified as right-hand glove and left-hand glove

6. Intended Use

Sterile Surgical Gloves-Powder Free

This single use sterile Surgical Gloves-Powder Free is intended for use in surgical procedures and to be worn once and then discarded. The glove is worn on the hand of surgeon and healthcare personnel to prevent contamination between healthcare personnel and the patient's blood, body fluids, secretions, waste or environment. The gloves are designed for transient use and are intended to be used in conjunction with invasive procedures.

The powder free gloves can be used for avoiding any risk due to powder in critical surgeries as an added precaution.

7. Product Size

PRODUCT	SIZE (Inch)
Sterile Latex Surgical Gloves Powder Free	5½, 6, 6½, 7, 7½, 8, 8½, 9

8. 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.

9. Contraindications

- Latex gloves are made of Natural rubber latex, which may cause allergic reactions including Latex Allergy – Anaphylactic if the user is allergic to latex.
- Gloves contain Natural Latex; persons who are sensitive to Latex should consult a physician before using

10. Precautions and warnings

- This product contains natural rubber latex which may cause allergic reactionsuch as latex allergy, including anaphylactic responses in some individuals
- Do not use if the pouch is torn or sterility is compromised
- Do not Re-sterilize – Re-sterilization can cause product damage / Contamination
- Do not Re Use - Reuse can cause infection, allergic reaction and poor barrier protection.

11. Intended User

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

12. Intended Patient Population

These sterile latex gloves are used for all patient population except in patients with known allergy to natural latex rubber.

13. Direction for Use

- Select the appropriate size Gloves for the hand.
- Takeout the Wallet from the pouch by peeling it off at the site of direction for open.
- Dry hand before donning the gloves
- 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.

14. Clinical Benefits

NRL or Natural Rubber Latex Gloves:

- Are competent barrier to protect against infections for both healthcare professionals and the patients.
- Are easy to put on comfortable to wear and provide adequate, durable protection.
- Have less after-use defects.
- Has significant greater satisfaction with regard to factors such as quality, safety and durability.
- Have good barrier integrity.
- Have good fit and comfort
- Have high tear propagation strength
- Have high tensile strength

15. Side Effects

- Latex Allergy
- Cross contamination
- Skin inflammation
- Skin irritation on the patient
- Impairment of Hand dexterity
- Redness
- Hands-Itchy and sore

16. Residual Risk

- Anaphylaxis, IgE-mediated allergic reactions
- Blood-Borne Infection, Post-operative wound infection
- Itchy skin and hives
- Inflammation, Toxic to environment

17. Method of Sterilization

- Ethylene Oxide and Gamma

18. Disposal Instruction

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

19. How Supplied

- Gloves are supplied as a pair and packed and identified as right-hand glove and left-hand glove

20. Explanation of symbols used on label

	Do not re-use		Contains or presence of latex rubber
	Consult Instructions for Use		Do not Re-sterilize
	Lot/Batch No		Sterilized by ethylene oxide
	Expiry Date		Sterilized by Gamma
	Date of Manufacture		Caution
	Do not use if package is opened or damaged		Keep away from sun light
 XXXX	CE Mark		Keep Dry
	Unique Device Identification		Temperature limit

	Beta Healthcare Products Pvt. Ltd. Plot No.21B, Cochin Special Economic Zone, Kakkanad, Kochi-682 037, Kerala, India. Tel: +91-484 2413340, boney@betahealthcare.com **www.betahealthcare.com**		Amstermed BV Saturnusstraat 46-62, Unit 032, 2132 HB Hoofddorp, The Netherlands. Phone: +31 23 5656337, Email: info@amstermed.nl Website: www.amstermed.nl
	One Pair		Size

1. Product Name

Sterile Latex Surgical Gloves- Powdered

2. Brand Name

Description	Powdered
Surgical Gloves –EO Sterile	Pristeen Pristeen++ Perfekto Protezione Hospicare
Surgical - Gamma	Pristeen Pristeen++

3. Name and Address of the manufacture:

Beta Healthcare Products Private Limited
Plot No.21B, Cochin Special Economic Zone,
Kakkanad, Kochi-682 037, Kerala, India.
Tel: +91-484 2413340, Fax: +91- 2413341
www.betahealthcare.com

4. Unique Device Identification (UDI)

Sl. No	Product Name	Size	GMN (Basic UDI-DI)	GTIN 13	Brand Name	GTIN 14
1	Surgical Gloves Powdered	6.0	8908000843LSGPD9A	8908000843011	Pristeen	G08908000843011
2		6.5		8908000843028		G08908000843028
3		7.0		8908000843035		G08908000843035
4		7.5		8908000843059		G08908000843059
5		8.0		8908000843080		G08908000843080
6		8.5		8908000843066		G08908000843066
7		9.0		8908000843073		G08908000843073

5. Product Description

The sterile latex surgical gloves powdered are manufactured with Natural Rubber Latex. These gloves are sterilized by using gaseous method (EO Gas) or Gamma irradiation method as per customer demands.

These latex gloves carry the following features:

- Sterile
- Curved finger shaped (Hand Specific, Right or Left)
- Micro-roughened texture finish
- Beaded and long cuff gloves.
- Pre-powdered USP absorbable corn-starch for powdered gloves
- Single Use
- Gloves specifications are as per EN 455-1, 2, 3, 4 / ASTM D 3577 standards.
- Anatomical shape

These gloves are supplied as a pair and packed and identified as right-hand glove and left-hand glove

6. Intended Use

Sterile Surgical Gloves-Powdered

This single use Sterile Surgical Gloves-Powdered is intended for use in surgical procedures and to be worn once and then discarded. The glove is worn on the hand of surgeon and healthcare personnel to prevent contamination between healthcare personnel and the patient's blood, body fluids, secretions, waste or environment. The gloves are designed for transient use and are intended to be used in conjunction with invasive procedures.

The glove is pre powdered with absorbable USP grade corn starch for easy donning. Bio-absorbable USP grade corn starch is generally accepted as a safe donning agent

7. Product Size

PRODUCT	SIZE (Inch)
Sterile Latex Surgical Gloves Powdered	5½, 6, 6½, 7, 7½, 8, 8½, 9

8. 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.

9. Contraindications

- Latex gloves are made of Natural rubber latex, which may cause allergic reactions including Latex Allergy – Anaphylactic if the user is allergic to latex.

- Gloves contain Natural Latex; persons who are sensitive to Latex should consult a physician before using
- Sterile Latex Surgical Gloves Powdered contain Powder content, persons who are sensitive to powder may develop allergy towards the powder content.

10. Precautions and warnings

- This product contains natural rubber latex which may cause allergic reaction such as latex allergy, including anaphylactic responses in some individuals
- Do not use if the pouch is torn or sterility is compromised
- Do not Re-sterilize – Re-sterilization can cause product damage / Contamination
- Do not Re Use - Reuse can cause infection, allergic reaction and poor barrier protection.
- After donning remove powder by wiping gloves thoroughly with wet sterile sponge or any other effective method

11. Intended User

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

12. Intended Patient Population

These sterile latex gloves are used for all patient population except in patients with known allergy to natural latex rubber.

13. Direction for Use

- 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.
- Dry hand before donning the gloves
- Wear the gloves as left to the Left hand & Right to the Right Hand as denoted on the wallet.
- After donning remove powder by wiping gloves with a sterile wet sponge or any other effective methods.
- Must check the date of manufacturing and expiry date
- Adjust the gloves as needed.

14. Clinical Benefits

NRL or Natural Rubber Latex Gloves:

- Are competent barrier to protect against infections for both healthcare professionals and the patients.

- Are easy to put on comfortable to wear and provide adequate, durable protection.
- Have less after-use defects.
- Has significant greater satisfaction with regard to factors such as quality, safety and durability.
- Have good barrier integrity.
- Have good fit and comfort
- Have high tear propagation strength
- Have high tensile strength

15. Side Effects

- Powder Allergy
- Latex Allergy
- Cross contamination
- Skin inflammation
- Skin irritation on the patient
- Impairment of Hand dexterity
- Redness
- Hands-Itchy and sore

16. Residual Risk

- Anaphylaxis, IgE-mediated allergic reactions
- Blood-Borne Infection, Post-operative wound infection
- Itchy skin and hives
- Inflammation, Toxic to environment
- Respiratory tract Diseases

17. Method of Sterilization

- Ethylene Oxide and Gamma

18. Disposal Instruction

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

19. How Supplied

- Gloves are supplied as a pair and packed and
- identified as right-hand glove and left-hand glove

20. Explanation of symbols used on label

	Do not re-use	LATEX	Contains or presence of latex rubber
	Consult Instructions for Use	STERILIZE	Do not Re-sterilize
LOT	Lot/Batch No	STERILE EO	Sterilized by ethylene oxide
	Expiry Date	STERILE R	Sterilized by Gamma
	Date of Manufacture		Caution
	Do not use if package is opened or damaged		Keep away from sun light
CE XXXX	CE Mark		Keep Dry
Unique Device Identification	Unique Device Identification	5°C 32°C	Temperature limit
	Beta Healthcare Products Pvt. Ltd. Plot No.21B, Cochin Special Economic Zone, Kakkanad, Kochi-682 037, Kerala, India. Tel: +91-484 2413340, boney@betahealthcare.com www.betahealthcare.com	EC REP	Amstermed BV Saturnusstraat 46-62, Unit 032, 2132 HB Hoofddorp, The Netherlands. Phone: +31 23 5656337, Email: info@amstermed.nl Website: www.amstermed.nl
1 Pair	One Pair		Size

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Succeed with Quality

CERTIFICATE

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH awards this **quality**austria certificate to the following organisation:

This **quality**austria certificate confirms the application and further development of an effective

QUALITY MANAGEMENT SYSTEM
complying with the requirements of standard
ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes

BETA HEALTHCARE PRODUCTS PVT. LTD.
Plot NO-21B, COCHIN SPECIAL ECONOMIC ZONE, KAKKANAD, KOCHI – 682037, KERALA, INDIA

incl. site: Plot No. 39 A, COCHIN SPECIAL ECONOMIC ZONE, KAKKANAD, KOCHI – 682037, KERALA, INDIA

Manufacturing, sales and distribution of Latex and Nitrile Surgical and Examination Gloves (Sterile, Non-Sterile, Powdered and Powder Free)

The validity of the **quality**austria certificate will be maintained by annual surveillance audits and one renewal audit after three years.

Registration No.: 00279/0

Date of initial issue: 07 March 2018

Valid until: 06 March 2024

Vienna, 11 June 2021

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH,
AT-1010 Vienna, Zelinkagasse 10/3

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