



BETA HEALTHCARE PRODUCTS PVT LTD		
PRODUCT SPECIFICATION		
STERILE LATEX SURGICAL GLOVES POWDERED- 18 GRAM		
Issue No: 01	Issue Date: 27/04/2022	DOC No : BHPL/PS/08

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,
Kakkanad Kochi-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 rather than 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. **INTENDED USE:**

- Gloves intended for use in surgical work and to be worn once and then discarded. The glove is worn on the 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 anaphylactic responses in some individuals.
- After donning remove powder by wiping gloves thoroughly with a sterile wet sponge, sterile wet towel or other effective method.
- Reuse of gloves may cause infection, allergic reaction and poor barrier protection.



BETA HEALTHCARE PRODUCTS PVT LTD		
PRODUCT SPECIFICATION		
STERILE LATEX SURGICAL GLOVES POWDERED- 18 GRAM		
Issue No: 01	Issue Date: 27/04/2022	DOC No : BHPL/PS/08

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



BETA HEALTHCARE PRODUCTS PVT LTD		
PRODUCT SPECIFICATION		
STERILE LATEX SURGICAL GLOVES POWDERED- 18 GRAM		
Issue No: 01	Issue Date: 27/04/2022	DOC No : BHPL/PS/08

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

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	24MPa/min	Min.18 MPa/min
Elongation percentage	750%	560%

Powder Content

- Reference Standard: EN 455-3:2015
- Specification: $\leq 15 \text{ mg / dm}^2$

Protein Content

- Reference Standard: EN 455-3:2015
- Specification: $\leq 50 \text{ ug/dm}^2$

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: $\geq 1.2 \text{ N/15mm}$

Type of opening of the pouch- Peel open



BETA HEALTHCARE PRODUCTS PVT LTD		
PRODUCT SPECIFICATION		
STERILE LATEX SURGICAL GLOVES POWDERED- 18 GRAM		
Issue No: 01	Issue Date:27/04/2022	DOC No : BHPL/PS/08

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



BETA HEALTHCARE PRODUCTS PVT LTD		
PRODUCT SPECIFICATION		
STERILE LATEX SURGICAL GLOVES POWDER FREE- 18 GRAM		
Issue No: 01	Issue Date: 27/04/2022	DOC No : BHPL/PS/07

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 rather than 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. **INTENDED USE:**

- Gloves intended for use in surgical work and to be worn once and then discarded. The glove is worn on the 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 anaphylactic responses in some individuals.
- Reuse of gloves may cause infection, allergic reaction and poor barrier protection.



BETA HEALTHCARE PRODUCTS PVT LTD		
PRODUCT SPECIFICATION		
STERILE LATEX SURGICAL GLOVES POWDER FREE- 18 GRAM		
Issue No: 01	Issue Date: 27/04/2022	DOC No : BHPL/PS/07

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	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



BETA HEALTHCARE PRODUCTS PVT LTD		
PRODUCT SPECIFICATION		
STERILE LATEX SURGICAL GLOVES POWDER FREE- 18 GRAM		
Issue No: 01	Issue Date: 27/04/2022	DOC No : BHPL/PS/07

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/dm²

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



BETA HEALTHCARE PRODUCTS PVT LTD		
PRODUCT SPECIFICATION		
STERILE LATEX SURGICAL GLOVES POWDER FREE- 18 GRAM		
Issue No: 01	Issue Date: 27/04/2022	DOC No : BHPL/PS/07

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



.....CUT TO OPEN.....



DO NOT USE IF PACKAGE IS OPENED OR DAMAGED

pristeen[®]
Surgical Gloves

STERILE

SURGICAL

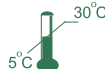
POWDER FREE

- ✓ Quality as per ASTM D 3577
BS EN 455-1,2,& 3 standards
- ✓ Anatomically shaped
curved fingers for user comfort
- ✓ Beaded cuffend
- ✓ Micro textured surface for better grip
- ✓ Powder free for easy donning
- ✓ Sterilized with ethylene oxide

Single use.
Sterile unless package is damaged or opened.
Store in a cool, dry place, away from direct sunlight & ozone.
This product contains natural rubber latex which
may cause allergic reaction including anaphylactic
responses in some individuals.
Risk of reuse : May cause infection, allergic
reaction and poor barrier protection.



Size : **6.0**
Batch No. : **LOT**
Mfg.date :
Exp.date :
Sterile Date : **STERILE EO**



This product is for
single use only

Protect from heat, Humidity,
Strong Light and Ozone



ISO 9001:2015

ISO 13485:2016

EC REP

Amstermed B.V.
Saturnusstraat 46-62,
Unit 032,
2132 HB Hoofddorp,
The Netherlands
Ph:+31 23 5656337,
Web:www.amstermed.nl

MADE IN INDIA

Manufactured By:

Beta Healthcare Products (P) Ltd.
Plot No - 21B
Cochin Special Economic Zone
Kakkanad, Cochin - 682037
+91-484-2413340
boney@betahealthcare.com
www.betahealthcare.com

MFG.Licence No : EKM/03/491/2006
SRN No. : IN-MF-000019439

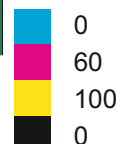


BL/S/18

Rev.No:04



100% PANTONE 356 U



.....CUT TO OPEN.....



DO NOT USE IF PACKAGE IS OPENED OR DAMAGED

pristeen®

Surgical Gloves

STERILE

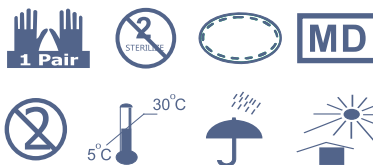
SURGICAL POWDERED

- ✓ Quality as per ASTM D 3577
BS EN 455-1,2,& 3 standards
- ✓ Anatomically shaped
curved fingers for user comfort
- ✓ Beaded cuffend
- ✓ Micro textured surface for better grip
- ✓ Powdered using absorbable
U.S.P. corn starch
- ✓ Sterilized with ethylene oxide

Single use.
Sterile unless package is damaged or opened.
Store in a cool, dry place, away from direct sunlight & ozone.
This product contains natural rubber latex which
may cause allergic reaction including anaphylactic
responses in some individuals.
After donning, remove the powder by wiping gloves
thoroughly with a sterile wet sponge or other effective methods.
Risk of reuse : May cause infection, allergic
reaction and poor barrier protection.



Size : **6.0**
Batch No. : **LOT** :
Mfg.date :
Exp.date :
Sterile Date : **STERILE EO** :



CE 2460 LATEX
ISO 9001:2015 ISO 13485:2016

EC REP

Amstermed B.V.
Saturnusstraat 46-62,
Unit 032,
2132 HB Hoofddorp,
The Netherlands
Ph:+31 23 5656337,
Web:www.amstermed.nl
MADE IN INDIA

Manufactured By:

Beta Healthcare Products (P) Ltd.
Plot No - 21B
Cochin Special Economic Zone
Kakkanad, Cochin - 682 037
+91-484-2413340
boney@betahealthcare.com
www.betahealthcare.com

MFG.Licence No : EKM/03/491/2006
SRN No. : IN-MF-000019439

BL/S/01



Rev.No:04



60	0	60	100
40	60	100	0
0	100	0	0
40	0	0	0