Certificate

Factual Assessments - Global Certifications

Royal Stancert Inc.

This is to certify that the technical documentation for the product:

Sterile Medical / Surgical and Hospital Linen Items

(Product Details as per Annexures)

Manufactured by:

Bharti Textiles

27, Shazada Bagh Extension, Daya Basti, Delhi - 110035 India.

Complies with the applicable requirements of **Medical Devices Directive 93/42/EEC**

The technical documentation / inspection / test results comply with the requirements of **Medical Devices Directive (MDD)**, hence manufacturer`s declaration of conformity according to above directive is accepted. **Bharti Textiles.** can place the CE marking as per laid down regulations on the products listed in Annexure

Certificate No.: CE-RS-1707-2046
Date of Issue: 04-07-2017
Date of Expiry: 03-07-2020
Surveillance Frequency: Annual

Global Euro Accreditation Centre GEAC Global Euro Accreditation Centre

PAC-GEAC-1506-299

RSI - GGN- 1272/ XVGN

CE

172046

International Operations: Eschersheimer Landstr. 42, 60322 Frankfurt am Main, Frankfurt, Germany.
Email: info@royalstancert.net

This certificate remains the property of Royal Stancert Inc. and must be returned whenever demanded. The validity of this certificate can be verified at http://www.royalstancert.net. Royal Stancert Inc. is an independent system, product and personal assessment body. RSI is accredited by Global Euro Accreditation Centre, Georgia. (GCIN - 654)

Certificate

Factual Assessments - Global Certifications

Royal Stancert Inc.

Annexure1 to CE Conformity Certificate No. CE-RS-1707-2046

Products covered by this certificate:

1	Handloom Cotton Bandage Cloth / Rolled Bandages / Open Wove Bandage / Cut Bandages / W.O.W Bandage / Cotton Bandage
2	Handloom Cotton Gauze Absorbent / Gauze Swab
3	Absorbent Lint
4	Cotton Crepe Bandages / Crepe Bandage / Bandage Crepe
5	Abdominal Sponge / Laparotomy Sponge
6	Triangular Bandage
7	Absorbent Cotton Ribbon Gauze
8	Combined Dressing
9	Disposable Delivery Kit
10	Disposable OT Pack
11	Bed sheet
12	Pillow covers
13	Lab/ Doctor / Technician coat
14	Surgeon / Surgical / OT Gown
15	Surgeon Shirt & Pajama / Scrub Suit / OT Suit
16	Patient Shirt & Pajama / Patient Suit
17	Patient Gown
18	Draw Sheet
19	Trolley Cover
20	Abdominal Sheet
21	OT Sheet
22	Baby Sheet
23	Dressing Towel
24	OT Towel
25	Eye Sheet
26	Hole Sheet
27	Leggings
28	Spinal Sheet
29	Table Sheet
30	Counter Pen

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Global Euro Accreditation Centre
GEAC
Global Euro Accreditation Centre

PAC-GEAC-1506-299

Director (Certification)

RS1 - GGN- 1272/ XVGN

CE

172046

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Certificate

Factual Assessments - Global Certifications

Royal Stancert Inc.

Annexure2 to CE Conformity Certificate No. CE-RS-1707-2046

Products covered by this certificate:

31	Maternity Gown / Kangaroo Gown
32	Children Shirt & Pajama
33	Maxi
34	Gyane Sheet
35	Screen Cover
36	Shoe Cover
37	Cap
38	Face Mask
39	PVC / Plastic / Non-Woven Apron
40	PVC Draw Sheet
41	Dental Apron
42	Labour Kit
43	Cesarean Kit
44	HIV Kit
45	PPE Kit
46	Drape
47	Kelly's Pad
48	Orthopaedic Cast Padding(Soft Roll)
49	Suspensory Scrotal
50	Operating Pack
51	Polythene / Plastic Sheet
52	T-Shape Bandage
53	Dental Swab / Dental Napkin
54	Cover All
55	Operation Sheet

Certificate No.: CE-RS-1707-2046
Date of Issue: 04-07-2017
Date of Expiry: 03-07-2020
Surveillance Frequency: Annual

Director (Certification)

PAC-GEAC-1506-299

RSI - GGN- 1272/ XVGN

172046

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