

## FORM MD-3

[See sub-rule (2) of rule 20]

### Application for Grant of Licence to Manufacture for Sale and Distribution of Class A or Class B medical device

1. Name of Applicant: ALTUS HEALTH CARE SOLUTIONS
2. Nature and constitution of manufacturer: Partnership
3. (i) Corporate/ registered office address: M/s ALTUS HEALTH CARE SOLUTIONS,  
60/G/2, Near Lakshmi Kalyana Mandapam, Trichy Road,  
Sulur Block, Kannampalayam  
Coimbatore, Coimbatore, Tamil Nadu (India) - 641103  
Telephone No.: 9566395077 FAX: 9787759843 Email:  
altushealthcaresolutions@gmail.com
- (ii) Manufacturing site address/ Sterilization site address: M/s ALTUS HEALTH CARE SOLUTIONS ,  
No-60 G/2, Near Lakshmi Kalyana Mandapam, Trichy Road,  
Papampatti Pirivu, Coimbatore-641103.  
, Coimbatore, Tamil Nadu (India) - 641103  
Telephone No.: 9566395077 FAX: 9566395077
- (iii) Address for correspondence: M/s ALTUS HEALTH CARE SOLUTIONS,  
60/G/2, Near Lakshmi Kalyana Mandapam, Trichy Road,  
Sulur Block, Kannampalayam  
Coimbatore, Coimbatore, Tamil Nadu (India) - 641103  
Telephone No.: 9566395077 FAX: 9787759843 Email:  
altushealthcaresolutions@gmail.com
4. Details of medical device(s) to be manufactured

| S.No. | Details Of Device(s)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
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| 1     | <p><b>1. Generic Name :</b>STERILE SURGICAL DRAPE IS 17334</p> <p><b>2. Brand Name(if registered under the Trade Marks Act, 1999) :</b>Altus health care solutions</p> <p><b>3. Notified Category :</b>Surgical Dressings</p> <p><b>4. Class of Medical Device :</b>Class B</p> <p><b>5. Shelflife :</b>3 YEARS</p> <p><b>6. Sterilization:</b>Sterilized</p> <p><b>7. Contains Drugs:</b>No</p> <p><b>8. Medical Device Grouping Category :</b> Family</p> <p><b>9. Grouping Description:</b> SURGICAL DRESSINGS</p> <p><b>10. Intended Use :</b>A surgical drape &amp; drape accessories is a device made of natural or synthetic materials intended to be used as a protective patient covering to isolate a site of surgical incision from microbial &amp; other contamination.</p> <p><b>11. Product Description:</b> The Sterile Surgical Drape shall consist of rolled absorbent Nonwoven fabric. The Drape shall be almost odourless. Bandage roll should be reasonably free from loose fibres and particles. The rolls shall be medical blue, medical green &amp; good white, clean and free from substances liable to cause tendering during storage. The product shall be free from toxic or harmful substance</p> <p><b>12. Material of Construction:</b> SMS,SMMS, NONWOVEN &amp; POLYTHENE ( AS PER THE REQUIREMENT OF SURGICAL DRAPE IS 17334)</p> <p><b>13. Dimension:</b> Length-70Cm to 260Cm, Breath-50Cm - 160Cm &amp; GSM - 30Gsm - 70Gsm</p> <p><b>14. Storage Condition:</b> Protection from moisture and dust. Store at ambient Temperature 25 C to 30 C</p> <p><b>14. Pack Size:</b> 1's</p> <p><b>15. Accessory:</b> NIL</p> <p><b>16. Model No. :</b>NIL</p> <p><b>17. Equivalence to prediecte device :</b>Yes</p> |

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| 2 | <p><b>1. Generic Name :</b>STERILE SURGICAL GOWN IS 17334</p> <p><b>2. Brand Name(if registered under the Trade Marks Act, 1999) :</b>Altus health care solutions</p> <p><b>3. Notified Category :</b>Surgical Dressings</p> <p><b>4. Class of Medical Device :</b>Class B</p> <p><b>5. Shelflife :</b>3 YEARS</p> <p><b>6. Sterilization:</b>Sterilized</p> <p><b>7. Contains Drugs:</b>No</p> <p><b>8. Medical Device Grouping Category :</b> Family</p> <p><b>9. Grouping Description:</b> SURGICAL DRESSINGS</p> <p><b>10. Intended Use :</b>A sterile garment made of natural and/or synthetic materials intended for surgical procedures to help protect both the patient and operating room personnel from the transfer of microorganisms, body fluids, and particulate material.</p> <p><b>11. Product Description:</b> The Sterile Surgical Gown shall consist of rolled absorbent Nonwoven fabric. The Surgical Gown shall be almost odourless. Bandage roll should be reasonably free from loose fibres and particles. The rolls shall be medical blue, medical green &amp; good white, clean and free from substances liable to cause tendering during storage. The product shall be free from toxic or harmful substance</p> <p><b>12. Material of Construction:</b> AS PER REQUIREMENT OF SURGICAL GOWN IS 17334 (SMS,SMMS &amp; NONWOVEN))</p> <p><b>13. Dimension:</b> Length (90 cm-120 cm) X Width ( 90 cm-120 cm) X Breath (125-170 cm)</p> <p><b>14. Storage Condition:</b> Protection from moisture and dust. Store at ambient Temperature 25 C to 30 C</p> <p><b>14. Pack Size:</b> 1's</p> <p><b>15. Accessory:</b> NIL</p> <p><b>16. Model No. :</b>NIL</p> <p><b>17. Equivalence to prediecte device :</b>Yes</p>                                                                                           |
| 3 | <p><b>1. Generic Name :</b>STERILE PATIENT GOWN IHS</p> <p><b>2. Brand Name(if registered under the Trade Marks Act, 1999) :</b>Altus health care solutions</p> <p><b>3. Notified Category :</b>Otherspersonal protective Equipment</p> <p><b>4. Class of Medical Device :</b>Class A</p> <p><b>5. Shelflife :</b>3 YEARS</p> <p><b>6. Sterilization:</b>Sterilized</p> <p><b>7. Contains Drugs:</b>No</p> <p><b>8. Medical Device Grouping Category :</b> Family</p> <p><b>9. Grouping Description:</b> PPE</p> <p><b>10. Intended Use :</b>A garment made of natural and/or synthetic materials (e.g.,paper, cloth, plastic) intended to be worn by patients in a clinical setting (e.g., during hospitalization, during examination in a doctor's office). A patient gown is usually short-sleeved and may be closed by ties at the back/side of the garment.</p> <p><b>11. Product Description:</b> The Sterile Patient Gown shall consist of rolled absorbent Nonwoven fabric. The Gown shall be almost odourless. Bandage roll should be reasonably free from loose fibres and particles. The rolls shall be medical blue, medical green &amp; good white, clean and free from substances liable to cause tendering during storage. The product shall be free from toxic or harmful substance</p> <p><b>12. Material of Construction:</b> SMS,SMMS,NONWOVEN &amp; POLYTHENE ( AS PER THE REQUIREMENT OF PATIENT GOWN -INHOUSE SPECIFICATION))</p> <p><b>13. Dimension:</b> Length (90 cm-120 cm) X Width ( 90 cm-120 cm) X Breath (125-170 cm)</p> <p><b>14. Storage Condition:</b> Protection from moisture and dust. Store at ambient Temperature 25 C to 30 C</p> <p><b>14. Pack Size:</b> 1's</p> <p><b>15. Accessory:</b> NIL</p> <p><b>16. Model No. :</b>NIL</p> <p><b>17. Equivalence to prediecte device :</b>Yes</p> |

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| 4 | <p><b>1. Generic Name :</b>STERILE PERSONAL PROTECTIVE EQUIPMENT (PPE KIT)</p> <p><b>2. Brand Name(if registered under the Trade Marks Act, 1999) :</b>Altus health care solutions</p> <p><b>3. Notified Category :</b>Otherspersonal protective Equipment</p> <p><b>4. Class of Medical Device :</b>Class B</p> <p><b>5. Shelflife :</b>3 YEARS</p> <p><b>6. Sterilization:</b>Sterilized</p> <p><b>7. Contains Drugs:</b>No</p> <p><b>8. Medical Device Grouping Category :</b> Family</p> <p><b>9. Grouping Description:</b> PPE</p> <p><b>10. Intended Use :</b>PPE kit used to acts as a barrier between infectious materials such as viral and bacterial contaminants and skin, mouth, nose, or eyes. It refers to protective clothing, helmets, gloves, face shields, goggles, facemasks and/or respirators or other equipment designed to protect the wearer from injury or the spread of infection or illness</p> <p><b>11. Product Description:</b> Personal Protective Equipment's (PPEs) are protective gears designed to safeguard the health of workers by minimizing the exposure to a biological agent..</p> <p><b>12. Material of Construction:</b> SMS, SMMS &amp; NONWOVEN (Packed with ( Personal Protection Kit - 1).Patient Gown - 1 No(Size: 160Cm x 80Cm), 2).Operating Room Shoe Cover - (Size: 55Cm x 40Cm) 3).Surgical Face Face Mask - 1 No 4).Gloves - Pair 5).Surgical Cap - I Nos))</p> <p><b>13. Dimension:</b> Packed with ( Personal Protection Kit - 1).Patient Gown - 1 No(Size: 160Cm x 80Cm), 2).Operating Room Shoe Cover - (Size: 55Cm x 40Cm) 3).Surgical Face Face Mask - 1 No 4).Gloves - Pair 5).Surgical Cap - I Nos))</p> <p><b>14. Storage Condition:</b> Protection from moisture and dust. Store at ambient Temperature 25 C to 30 C</p> <p><b>14. Pack Size:</b> 1's</p> <p><b>15. Accessory:</b> NIL</p> <p><b>16. Model No. :</b>NIL</p> <p><b>17. Equivalence to predicate device :</b>Yes</p>                                                                                                                                                                                                                                                                       |
| 5 | <p><b>1. Generic Name :</b>STERILE X-RAY DETECTABLE LAPAROTOMY SPONGES IS 10829</p> <p><b>2. Brand Name(if registered under the Trade Marks Act, 1999) :</b>Altus health care solutions</p> <p><b>3. Notified Category :</b>Surgical Dressings</p> <p><b>4. Class of Medical Device :</b>Class B</p> <p><b>5. Shelflife :</b>3 YEARS</p> <p><b>6. Sterilization:</b>Sterilized</p> <p><b>7. Contains Drugs:</b>No</p> <p><b>8. Medical Device Grouping Category :</b> Family</p> <p><b>9. Grouping Description:</b> SURGICAL DRESSINGS</p> <p><b>10. Intended Use :</b>X-Ray Detectable Laparotomy Sponges is used in surgical dressing procedures to absorb blood and other fluids as well as clean wounds &amp; Used to secure dressings and other wounds care applications</p> <p><b>11. Product Description:</b> X-ray detectable laparotomy sponges shall consist of folded absorbent gauze, to which is attached a non-toxic and distinctively coloured monofilament or multifilament X-ray detectable member. The absorbent gauze shall consist of cotton cloth of plain or leno 'weaves, bleached to white, clean and reasonably free from weaving defects, cotton leaf and shell. The gauze shall be almost odourless. -The X-ray detectable member shall be distinctively coloured and reasonably free from loose fibres and particles; when attached, it shall not impair the softness or flexibility of the gauze. The X-ray detectable member consists of not less than 55 percent of barium sulphate or a quantity of any other suitable material giving a comparable X-ray opacity.</p> <p><b>12. Material of Construction:</b> 100% COTTON, AS PER THE REQUIREMENT OF X-RAY DETECTABLE LAPAROTOMY SPONGES IS 10829, X-ray detectable member consists of not less than 55 percent of barium sulphate</p> <p><b>13. Dimension:</b> Length (30cm x 60Cm) Width ( 30cmx60cm) No.of Ply (4,6,8,12 &amp; 16)</p> <p><b>14. Storage Condition:</b> Protection from moisture and dust. Store at ambient Temperature 25 C to 30 C</p> <p><b>14. Pack Size:</b> 1's , 6's , 10's, 12's</p> <p><b>15. Accessory:</b> NIL</p> <p><b>16. Model No. :</b>NIL</p> <p><b>17. Equivalence to predicate device :</b>Yes</p> |

5. Whether substantial equivalence to a predicate device is claimed: refer the table

6. Fee paid on 17-JUN-2025, null 10000.00 receipt/challan/transaction id 20250617030795.

7. I have enclosed the documents as specified in the Fourth Schedule of Medical Devices Rules, 2017.

8. I hereby state and undertake that:

(i) the manufacturing site is already for audit or shall be ready for audit on in accordance with the requirements of Medical Devices Rules, 2017.

(ii) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

Place:

Signature

Date: 17-Jun-25

(Name and Designation)