

FORM MD-7

[See sub-rule (1) of rule 21 and sub-rule (2) of rule 21]

Application for Grant of Licence to Manufacture for Sale or for Distribution of Class C or Class D medical device

1. Name of Applicant: Shagun Cares Inc.
2. Nature and constitution of manufacturer: Proprietary
3. (i) Corporate/ registered office address: M/s Shagun Cares Inc.,
Shed No 27, DSIIDC Industrial Complex, Rohtak Road,
Nangloi
Nangloi, --, Delhi (India) - 110041
Telephone No.: 11-25477777 FAX: 11-25477777
- (ii) Manufacturing site address: M/s Shagun Cares Inc.,
Shagun Cares Inc. Shed No C-27, DSIIDC Industrial
Complex, Rohtak Road, Nangloi (India) - 110041
, West Delhi, Delhi (India) - 110041
Telephone No.: 1125477777 FAX: 1125477777
- (iii) Address for correspondence: M/s Shagun Cares Inc.,
Shagun Cares Inc. Shed No C-27, DSIIDC Industrial
Complex, Rohtak Road, Nangloi (India) - 110041
, West Delhi, Delhi (India) - 110041
Telephone No.: 1125477777 FAX: 1125477777

4. Details of medical device(s) to be manufactured

S.No.	Details Of Device(s)
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1

1. Generic Name :HIP REPLACEMENT SYSTEM
2. Brand Name(if registered under the Trade Marks Act, 1999) :NIL
3. Notified Category :Orthopaedic Implants
4. Class of Medical Device :Class C
5. Shelflife :Non Sterile : NIL , STERILE : 5 Years
6. Sterilization:Both
7. Contains Drugs:No
8. Medical Device Grouping Category : System
9. Grouping Description: Hip Prosthesis system is used to cure Deformities in Proximal part of Femur and Acetabulum area
10. Intended Use :Hip Prosthesis system is used to cure Deformities in Proximal part of Femur and Acetabulum area
11. Product Description: Thompson Hip prosthesis 32 mm to 65 mm Austin moor Hip prosthesis 32 mm to 65 mm Bipolar hip prosthesis (cementing and uncementing 32 mm to 65 mm Modular Bipolar hip prosthesis (cementing and uncementing 32 mm to 65 mm Cup of modular bipolar 32 mm to 65 mm Hip Cup (cementing and uncementing 32 mm to 75 mm Modular femoral head 20mm to 40 mm GenX Femoral Head 20mm to 40 mm Muller stem (cementing and uncementing Small , Medium Large Long stem (cementing and uncementing 200,250,300 mm Revision Stem (cementing and uncementing 200,250,300 mm 9 to 17 mm Hip stem (cementing and uncementing OX , XL , 1, 2, 3, 4, Gen X Hip Stem (cementing and uncementing 08,09,10,11,12,13,14,15,16,17,18 Tumour hip spacer (cementing and uncementing 30 to 200 mm 15 mm to 30 mm Tumour spacer Expandable (cementing and uncementing 30 to 200 mm 15 mm to 30 mm Tumour hip stem (cementing and uncementing 50 to 200 mm 7to15 mm Tumour hip resection Neck (cementing and uncementing Small , Medium Large Centralizers 6 to 18 mm Cement stopper 20 to 40 mm Liner 20 mm to 75 mm Acetabulum cup 20 mm to 75 mm Cemented cup 20 mm to 65 mm Custom Made Hip Small , Medium, Large Partial Hip Replacement Small , Medium, Large Mesh for Acetabulum Cup Small , Medium, Large Expandable Hip Replacement Small , Medium, Large
12. Material of Construction: Stainless steel , Titanium , Cobalt Chrome , UHMWPE , Peek
13. Dimension:
14. Storage Condition: Room Temperature
14. Pack Size: 1 , 5 , 10 , 50 , 100
15. Accessory: NIL
16. Model No. :NIL
17. Equivalence to prediecte device :No

2

1. Generic Name :KNEE REPLACEMENT SYSTEM
2. Brand Name(if registered under the Trade Marks Act, 1999) :NIL
3. Notified Category :Orthopaedic Implants
4. Class of Medical Device :Class C
5. Shelflife :Non Sterile : NIL , STERILE : 5 Years
6. Sterilization:Both
7. Contains Drugs:No
8. Medical Device Grouping Category : System
9. Grouping Description: Knee Replacement system is used to cure deformities and fractures of knee
10. Intended Use :Knee Replacement system is used to cure deformities and fractures of knee
11. Product Description: Tumour Knee Spacer (cementing and uncementing) length 30 to 200 mm Dia 15 to-35 mm Tumour Knee Spacer Expandable (cementing and uncementing) length 30 to 200 mm Dia 15 to-35 mm Tumour knee stem (cementing and uncementing) length 50 to 200 mm 7to30 mm Hing Pin Small, medium ,large Condoyle tumour knee Distal femur Small, medium ,large Condoyle tumour knee proximal knee Small, medium ,large Tumour knee with total hip resection(cementing and uncementing) Small, medium ,large Revision Knee Femur Small , Medium, Large Revision knee tibia Small , Medium, Large Revision Knee Spacer Small , Medium, Large Knee Femur Part Small , Medium, Large Knee Tibia Part Small , Medium, Large Spacer Small , Medium, Large Expandable knee Small , Medium, Large Custom made Knee Small , Medium, Large Diaphyseal spacer 20 to 120 mm 18 to 30 mm Bush 10 TO 30 MM 18 to 30 mm Knee stem (cementing and uncementing) Dia 7to15 mm length 100 to 200 mm 7to30 mm Ankle Implant Small , Medium , Large Partial Knee Small , Medium , Large Custom made tibia Small , Medium , Large Custom made Femur Small , Medium , Large Rotating Platform tibia knee Small , medium , large Rotating platform femur knee Small , medium , large Expandable tibia knee Small , medium , large Expandable femur knee Small , medium , large
12. Material of Construction: Stainless steel , Titanium , Cobalt Chrome , UHMWPE , Peek
13. Dimension:
14. Storage Condition: Room Temperature
14. Pack Size: 1 , 5 , 10 , 50 , 100
15. Accessory: NIL
16. Model No. :NIL
17. Equivalence to prediecte device :No

3

1. Generic Name :SHOULDER REPLACEMENT SYSTEM
2. Brand Name(if registered under the Trade Marks Act, 1999) :NIL
3. Notified Category :Orthopaedic Implants
4. Class of Medical Device :Class C
5. Shelflife :Non Sterile : NIL , STERILE : 5 Years
6. Sterilization:Both
7. Contains Drugs:No
8. Medical Device Grouping Category : System
9. Grouping Description: Shoulder Replacement system is used to cure Deformities or Fracture in Shoulder area
10. Intended Use :Shoulder Replacement system is used to cure Deformities or Fracture in Shoulder area
11. Product Description: Shoulder Head 28 mm to 44 mm Shoulder Neck (cementing and uncementing) Small, medium ,large Shoulder Stem (cementing and uncementing) 85 to 150 mm 5 to 9 mm Tumour Shoulder spacer (cementing and uncementing) 30 mm to 200 mm 18 to 25 mm Tumour shoulder stem (cementing and uncementing) 85 to 150 mm 5 to 14 mm Shoulder centralizer Dia 08 to 13 mm 10 to 13 mm Tumour Shoulder Neck(cementing and uncementing) Small , medium , large Reverse Shoulder (cementing and uncementing) Small , medium , large Expandable Shoulder (cementing and uncementing) Small , medium , large Custom Made Shoulder (cementing and uncementing) Small , medium , large Diaphyseal spacer (cementing and uncementing) 20 to 120 mm 18 to 30 mm Glenoid (cementing and uncementing) Small , medium , large Scapula (cementing and uncementing) Small , Medium , large
12. Material of Construction: Stainless steel , Titanium , Cobalt Chrome , UHMWPE , Peek
13. Dimension:
14. Storage Condition: Room Temperature
14. Pack Size: 1 , 5 , 10 , 50 , 100
15. Accessory: NIL
16. Model No. :NIL
17. Equivalence to prediecte device :No

4	<p>1. Generic Name :ELBOW REPLACEMENT SYSTEM</p> <p>2. Brand Name(if registered under the Trade Marks Act, 1999) :NIL</p> <p>3. Notified Category :Orthopaedic Implants</p> <p>4. Class of Medical Device :Class C</p> <p>5. Shelflife :Non Sterile : NIL , STERILE : 5 Years</p> <p>6. Sterilization:Both</p> <p>7. Contains Drugs:No</p> <p>8. Medical Device Grouping Category : System</p> <p>9. Grouping Description: Elbow Replacement system is used to Cure Deformities and Fractures in Elbow parts</p> <p>10. Intended Use :Elbow Replacement system is used to Cure Deformities and Fractures in Elbow parts</p> <p>11. Product Description: Hing Pin for elbow prosthesis Small , Medium Large Humorous part for elbow prosthesis Small , Medium , large Ulna part for elbow Small , Medium , large Condoyle part for elbow prosthesis Small , medium , large Normal Elbow Small , Medium , large Expandable Elbow Small , Medium , large Custom Made Elbow Small , Medium , large M.B.W Wrist Implants Small , medium , large P.I.P Implants Small , medium , large ADAMCO M.C.P Implants Small , medium , large ACAMO C.M.C Small , medium , large MOLANA M.T.P Implants Small , medium , large Bush Small , Medium , large Elbow Model No 2 Small , Medium , large</p> <p>12. Material of Construction: Stainless steel , Titanium , Cobalt Chrome , UHMWPE , Peek</p> <p>13. Dimension:</p> <p>14. Storage Condition: Room Temperature</p> <p>14. Pack Size: 1 , 5 , 10 , 50 , 100</p> <p>15. Accessory: NIL</p> <p>16. Model No. :NIL</p> <p>17. Equivalence to prediecte device :No</p>
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5. Whether substantial equivalence to a predicate device is claimed: refer the table

6. Fee paid on 12-APR-2019, INR 6000.00 receipt/challan/transaction id 1204190004160.

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 ready 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: 13-Apr-19

(Name and Designation)