

FORM MD-9

[See sub-rule (1) rule 25]

सत्यमेव जयते

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

Licence Number: MFG/MD/2019/000054

Endorsement No. 1

1. M/s Shagun Cares Inc., Shed No 27, DSIIDC Industrial Complex, Rohtak Road, NangloiNangloi, --, Delhi (India) -110041 Telephone No.: 11-25477777 FAX: 11-25477777 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at 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

2. Details of medical device(s) [Annexed]

3. The names, qualifications and experience of the competent technical staff responsible for the manufacture and testing of the above mentioned medical device(s): As per records maintain by the manufacturer

4. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

S.No.	CDSCO Details Of Device(s) SCO
1	Generic Name:HIP REPLACEMENT SYSTEM
	Model No.:NIL
	Intended Use: Hip Prosthesis system is used to cure Deformities in Proximal part of Femur and
	Acetabulum area
	Class of medical device: Class C
	Material of construction: Stainless steel, Titanium, Cobalt Chrome, UHMWPE, Peek
	Dimension(if any):
	Shelflife:Non Sterile : NIL , STERILE : 5 Years
	Sterile or Non sterile:Both
	Brand Name(if registered under the Trade Marks Act, 1999):NIL
2	Generic Name:KNEE REPLACEMENT SYSTEM
	Model No.:NIL
	Intended Use:Knee Replacement system is used to cure deformities and fractures of knee
	Class of medical device:Class C
	Material of construction:Stainless steel, Titanium, Cobalt Chrome, UHMWPE, Peek
	Dimension(if any):
	Shelflife:Non Sterile : NIL , STERILE : 5 Years
	Sterile or Non sterile:Both
	Brand Name(if registered under the Trade Marks Act, 1999):NIL

ANNEXURE

	Generic Name:SHOULDER REPLACEMENT SYSTEM
3	Model No.:NIL
	Intended Use: Shoulder Replacement system is used to cure Deformities or Fracture in
	Shoulder area
	Class of medical device:Class C
	Material of construction:Stainless steel, Titanium, Cobalt Chrome, UHMWPE, Peek
	Dimension(if any):
	Shelflife:Non Sterile : NIL , STERILE : 5 Years
	Sterile or Non sterile:Both
	Brand Name(if registered under the Trade Marks Act, 1999):NIL
4	Generic Name: ELBOW REPLACEMENT SYSTEM
-	Model No.:NIL
	Intended Use:Elbow Replacement system is used to Cure Deformities and Fractures in Elbow
	parts
	Class of medical device: Class C
	Material of construction:Stainless steel, Titanium, Cobalt Chrome, UHMWPE, Peek
	Dimension(if any):
	Shelflife:Non Sterile : NIL , STERILE : 5 Years
	Sterile or Non sterile:Both
	Brand Name(if registered under the Trade Marks Act, 1999):NIL

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Place:

Date:13-Mar-20

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Central Licensing Authority