



FORM MD -9

[See sub-rule (1) rule 25]

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

Licence Number.MFG/MD2024/345307

1. M/s TITANIUM ITALICA, #94/ 195, MAIN PEENYA INDUSTRIAL AREA , 10th MAIN ROAD, PHASE 2, BENGALURU -5600058 ,Telephone No.: 9350316449 FAX: 9350316449 has been licenced to manufacture for sale or distribution of the below listed medical device(s) at the premises situated at M/s TITANIUM ITALICA, #94/ 195, MAIN PEENYA INDUSTRIAL AREA , 10th MAIN ROAD, PHASE 2, BENGALURU -5600058,Telephone No.: 9350316449 FAX: 9350316449
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.

ANNEXURE

S.No.	Details Of Device(s)
1	<p>Generic Name: ORTHOPAEDIC ENDOPROSTHESIS Model No.: AUSTIN MOORE PROSTHESIS(ALL TYPES) - SS 316LVMDIA 36MM TO 62MM ,10* ACETABULAR CUP (ALL TYPES) - DIA 36MM TO 62MM .THOMPSON PROSTHESIS (ALL TYPES) - DIA 36MM TO 62MM , HIP PROSTHESIS (CEMENTED AND UNCEMENTED TYPES) - DIA 36MM TO 62MM.BIPOLAR PROSTHESIS (ALL TYPES) - DIA 36MM TO 62MM MULLER/XYLS STEM (ALL TYPES) - ALL SIZES ORTHOPAEDIC SHOULDER REPLACEMENT SYSTEM (ALL TYPES) - ALL SIZES ORTHOPAEDIC TUMOR DISTAL FEMUR - ALL SIZES , ORTHOPAEDIC TUMOR,CEMENTED TOTAL KNEE REPLACEMENT PROSTHESIS - ALL SIZES PROXIMAL TIBA - ALL SIZES ,ORTHOPAEDIC TUMOR GLENOID - ALL SIZES ,ORTHOPAEDIC RADIAL HEAD - ALL SIZES ,ORTHOPAEDIC EXPANDABLE IMPLANT (ALL TYPES) - ALL SIZES ORTHOPAEDIC CANCER IMPLANTS (ALL TYPES) • ALL SIZES ,ORTHOPAEDIC MODULAR BIPOLAR SYSTEM (ALL TYPES IN CEMENTED/ UNCEMENTED) - DIA 36MM TO 62MM . ORTHOPAEDIC ELBOW REPLACEMENT SYSTEM (ALL TYPES) - ALL SIZES, ORTHOPAEDIC CUSTOM MADE/TUMOR PROSTHESIS (ALL TYPES) - ALL SIZES. ORTHOPAEDIC B.CEMENT (ALL TYPES) - ALL SIZES ,ORTHOPAEDIC OTHER PROSTHESIS & IMPLANTS, ARTIFICIAL EXTERNAL DEVICES FOR POLIO ETC. - ALL SIZES Intended Use: ORTHOPAEDIC ENDOPROSTHESIS ARE USED IN HUMAN BODY FOR REPLACEMENT OF DEFECTIVE BONES/ TUMORS. Class of medical device: Class C and D Material of construction: Stainless Steel AISI 316L (LVM) , Cobalt Chromium alloy (ASTM F -75) & Titanium Ti-6Al-4V Dimension(if any): Shelf life: 60 MONTHS Sterile or Non sterile: Sterilized Brand Named (if registered under the Trade Marks Act, 1999): NIL</p>