



सत्यमेव जयते

FORM MD-6

[See sub-rule (4) of rule 20 and sub-rule (6) of rule 20]

Loan Licence to Manufacture for Sale or for Distribution of Class A or Class B medical device

Loan Licence Number: MFG/MD/2023/000402

1. M/s Biomedortho, 2nd Floor, A/242 Siddharth Annexe 3, VemaliVadodara, Vadodara, Gujarat (India) - 391740 Telephone No.: 9974279392 FAX: 9974279392 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s Biomedortho, Shed No 1 & 24 Raghuvver Industrial Estate Opp Jay Chemicals Odhav Road, Ahmedabad, Gujarat (India) - 382415 Telephone No.: 9974279392 FAX: 9974279392

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

3. 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	Generic Name:Resusable PINS & WIRE Instrument Set Model No.:PINS & WIRE Instrument System - K Wire Introducer, K-Wire Tractor Small, K-Wire Tractor Medium, K-Wire Tractor Large, K-Wire Bender, Wire Passer Small, Wire Passer Medium, Wire Passer Large,Steinman Pin Introducer With Chuck & Key - SS Chuck And Key, Steinmann Pin Holder 6", Steinmann Pin Holder 8", Steinmann Pin Holder 12", Steinmann Pin Holder 16", Wire Tightener Cum Twister Cum Cutter, Triple Drill Guide 2 MM,Bone Awl With Eye 3.5 MM - Cerclage Wire Tightener, Plier Cum Wire Bender Cum Wire Cutter 7", Plier Cum Wire Bender Cum Wire Cutter 9", Plier Cum Wire Bender Cum Wire Cutter 11", Shanz Pin Introducer, Wire Tighter With Two Pegs - Wire Cutter 10", Wire Cutter 11", Wire Holding Forcep for Cerclage Wire, Nose Plier Flat, Nose Plier Pointed, Wire Tightener/Twister,Wire Tightener Ordinary - Guide Wire Introducer With Four Pegs, Moon Plier (Side Cutting), Circular Wire Cutter, Pins & Wires Instrument Box With Implant Tray Intended Use:An orthopaedic, manual hand-held surgical instrument used during orthopaedic surgery to apply an appropriate tension to a wire that is being implanted. Class of medical device:Class A Material of construction:Stainless Steel 316L, 2205, 300 & 400 & 600 Series (ASTM F899) or Nitinol (ASTM F2063) OR Aluminum Alloy or Teflon (PTFE) OR Titanium Alloy / TiCP OR Acetal POM-C OR PEEK Dimension(if any):Various Dimensions Shelflife:NIL Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):BIOMEDORTHO, BIONEXORTHO

