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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/MD/2019/000117

1. M/s R.K.ENTERPRISES, Plot No- 543, GIDC WAGHODIAVADODARA, Vadodara, Gujarat (India) - 391760 Telephone No.: 9004001017 FAX: 9004001017 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s R.K. ENTERPRISES, Plot No- 543, Ground Floor, GIDC, WAGHODIA,, Vadodara, Gujarat (India) - 391760 Telephone No.: 9004001017 FAX: 9004001017
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	Generic Name:Bone Screw Model No.:NIL Intended Use:Bone screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device. Class of medical device:Class C Material of construction:Stainless Steel 316L Dimension(if any):Mini Screw Dia.- 1.5mm to 2.7mm Length - 4mm to 16mm Cortical Screw Dia.- 1.0 mm to 5.0mm Length - 6mm to 100mm Cannulated Bone Screw Dia.- 3.0mm to 7.3mm Length - 10mm to 120mm 16mm Thread/ 32mm Thread/ Fully Thread Cancellous Bone Screw Dia.- 3.0mm to 7.3mm Length - 10mm to 120mm 16mm Thread/ 32mm Thread/ Fully Thread Malleolar Screw Dia.- 4.5mm Length - 25mm to 80mm Herbert Screw Dia.- 3.0mm to 4.5mm Length - 25mm to 80mm Length - 10mm to 50mm Dynamic Hip Screw Length - 50mm to 125mm Proximal Bolt Dia.- 6.0mm to 8.0mm Length - 50mm to 130mm Interlocking Bolt Dia.- 2.5mm to 5.0mm Length - 12mm to 80mm Locking Head Screw Dia.- 2.0mm to 7.3mm Length - 06mm to 100mm Locking Head Cancellous Screw Dia.- 3.0mm to 7.3mm Length - 10mm to 100mm Button Button With Loop Suture Anchor Screw Dia.- 3.0mm to 5.0mm Interference Screw Round Head And Fully threaded Dia.- 6.0 mm to 11mm Length - 20mm to 40mm Transfix Screw Suture Post Bolt Length - 20mm to 40mm Shelflife:not applicable Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Not Applicable

2	Generic Name:Bone Screw Model No.:NIL Intended Use:Bone screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device. Class of medical device:Class C Material of construction:Titanium Dimension(if any):Mini Screw Dia.- 1.5mm to 2.7mm Length - 4mm to 16mm Cortical Screw Dia.- 1.0 mm to 5.0mm Length - 6mm to 100mm Cannulated Bone Screw Dia.- 3.0mm to 7.3mm Length - 10mm to 120mm 16mm Thread/ 32mm Thread/ Fully Thread Cancellous Bone Screw Dia.- 3.0mm to 7.3mm Length - 10mm to 120mm 16mm Thread/ 32mm Thread/ Fully Thread Malleolar Screw Dia.- 4.5mm Length - 25mm to 80mm Herbert Screw Dia.- 3.0mm to 4.5mm Length - 25mm to 80mm Length - 10mm to 50mm Dynamic Hip Screw Length - 50mm to 125mm Proximal Bolt Dia.- 6.0mm to 8.0mm Length - 50mm to 130mm Interlocking Bolt Dia.- 2.5mm to 5.0mm Length - 12mm to 80mm Locking Head Screw Dia.- 2.0mm to 7.3mm Length - 06mm to 100mm Locking Head Cancellous Screw Dia.- 3.0mm to 7.3mm Length - 10mm to 100mm Button Button With Loop Suture Anchor Screw Dia.- 3.0mm to 5.0mm Interference Screw Round Head And Fully threaded Dia.- 6.0 mm to 11mm Length - 20mm to 40mm Transfix Screw Suture Post Bolt Length - 20mm to 40mm Shelflife:not applicable Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Not Applicable
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3	Generic Name:Bone Plate Model No.:NIL Intended Use:Bone plates are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device. Class of medical device:Class C Material of construction:Stainless Steel 316L Dimension(if any):Small D.C. Plate Dia.- 3.5mm Length - 4 Hole to 16 Hole Narrow D.C. Plate Dia.- 4.5mm Length - 4 Hole to 18 Hole Broad D.C. Plate Dia.- 4.5mm Length - 4 Hole to 22 Hole Small L. C. D.C. Plate Dia.- 3.5mm Length - 4 Hole to 16 Hole Narrow L.C.D.C. Plate Dia.- 4.5mm Length - 4 Hole to 18 Hole Broad L.C..D.C. Plate Dia.- 4.5mm Length - 4 Hole to 22 Hole Small T- Plate Dia.- 3.5mm Length - 2 Hole to 10 Hole Oblique T- Plate Dia.- 3.5mm Length - 2 Hole to 10 Hole Left/Right Reconstruction Plate Dia.- 3.5mm,4.5mm Length - 4 Hole to 30 Hole Ellis Plate Dia.- 3.5mm Length - 2 Hole to 10 Hole Sherman Y Plate Dia.- 3.5mm Length - 2 Hole to 12 Hole Semi Tubular Plate Dia.- 4.5mm Length - 4 Hole to 16 Hole One Third Tubular Plate Dia.- 3.5mm Length - 3 Hole to 16 Hole Cloverleaf Plate Dia.- 4.5mm Length - 3 Hole to 12 Hole T-Buttress Plate Dia.- 4.5mm Length - 3 Hole to 16 Hole L-Buttress Plate Dia.- 4.5mm Length - 3 Hole to 16 Hole, Left/Right Condylar Buttress Plate Dia.- 4.5mm Length - 4 Hole to 16 Hole, Left/Right Lateral Tibia Plate Dia.- 4.5mm Length - 4 Hole to 16 Hole, Left/Right D.H.S Plate Dia.- 120° to 150° DC Hole/ Round Hole Long Barrel/ Short Barrel Length - 4 Hole to 16 Hole 95 Degree DCS Plate Dia.- 95° Length - 4 Hole to 16 Hole Lateral Tibia Locking Plate Length - 3 Hole to 16 Hole, Left/Right Anatomical Proximal Tibia Locking Plate Length - 3 Hole to 16 Hole, Left/Right Distal Femour Locking Plate Length - 5 Hole to 16 Hole, Left/Right Proximal Femour Locking Plate Length - 3 Hole to 16 Hole, Left/Right Reconstruction Locking Plate Length - 3 Hole to 20 Hole Phillos Locking Plate Length - 3 Hole to 12 Hole Clavical Hook Locking pLate Length - 4 Hole to 8 Hole, Left/Right Clavical Medial Locking Plate Length - 4 Hole to 8 Hole, Left/Right Superior Anterior Clavical Locking Plate Length - 4 Hole to 8 Hole, Left/Right Oblique T- Locking Plate Length - 3 Hole to 10 Hole Left/Right Small T- Locking plate Length - 3 Hole to 12 Hole T-Buttress Locking Plate Length - 3 Hole to 12 Hole L- Buttress Locking Plate Length - 3 Hole to 12 Hole Left/Right Small Locking Plate Length - 4 Hole to 12 Hole Narrow Locking Plate Length - 4 Hole to 16 Hole Broad Locking Plate Length - 4 Hole to 18 Hole Proximal Humerus Locking Plate Length - 3 Hole to 10 Hole Distal Tibial Medial Locking Plate Length - 3 Hole to 14 Hole Left/Right Distal Medial Locking Plate Length - 3 Hole to 14 Hole Left/Right Distal Tibia Locking Plate Length - 3 Hole to 14 Hole Left/Right Distal Humerus Dorsolateral With Support Locking Plate Length - 3 Hole to 14 Hole Left/Right Distal Humerus Dorsolateral Without Support Locking Plate Length - 3 Hole to 14 Hole Left/Right Distal Medial Humerus Metaphyseal Locking Plate Length - 3 Hole to 14 Hole Left/Right Posterior Medial Proximal Tibia Locking Plate Length - 2 Hole to 10 Hole Proximal Medial Tibia Locking Plate Length - 4 Hole to 10 Hole Calcaneal Locking Plate Length- Small,Medium,Large Pilon Locking Plate Length - 3 Hole to 10 Hole Volar Distal Radius Locking Plate Length - 3 Hole to 10 Hole Left/Right Olecranon Locking plate Length - 3 Hole to 10 Hole Left/Right Osteotomy Locking Plate Length - 3 Hole to 10 Hole Osteotomy Locking Block Length - 12mm to 18mm Proximal Femur Locking Plate Length - 3 Hole to 12 Hole Left/Right Lateral Proximal Tibia Locking Plate Length - 4 Hole to 16 Hole Left/Right Lateral Distal Tibia Locking Plate Length - 4 Hole to 16 Hole Left/Right Medial Proximal Tibia Locking Plate Length - 4 Hole to 16 Hole Left/Right Locking Distal Fibula Plate Length - 4 Hole to 10 Hole Left/Right Mini Plate With Gap Dia.- 1.5mm to 2.5mm Length - 2 Hole to 8 Hole Mini Continues Plate Dia.- 1.5mm to 2.5mm Length - 2 Hole to 50 Hole Mini T Plate Dia.- 1.5mm to 2.5mm Length - 2 Hole to 6 Hole Mini L Plate Dia.- 1.5mm to 2.5mm Length - 2 Hole to 6 Hole Mini Y Plate Dia.- 1.5mm to 2.5mm Length - Small,Big,Double Mini X Plate Dia.- 1.5mm to 2.5mm Length - 4 Hole Mini Z Plate Dia.- 1.5mm to 2.5mm Length - 4 Hole Mini Curved Plate Dia.- 1.5mm to 2.5mm Length - 4 Hole,6 Hole Mini Angular Plate Dia.- 1.5mm to 2.5mm Length - 4 Hole,6 Hole Mini Orbita Plate Dia.- 1.5mm to 2.5mm Length - 2 Hole to 6 Hole Mini Nose Plate Dia.- 1.5mm to 2.5mm H Shape,Y shape
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	Mini Chin Plate Dia.- 1.5mm to 2.5mm Chin Shape Mini H plate Dia.- 1.5mm to 2.5mm Length - 4 Hole to 10 Hole Eight Plate Small/medium/Large Suture Disk Conical and 2 Hole Shelflife:not applicable Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Not Applicable
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4	Generic Name:Bone Plate Model No.:NIL Intended Use:Bone plates are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device. Class of medical device:Class C Material of construction:Titanium Dimension(if any):Small D.C. Plate Dia.- 3.5mm Length - 4 Hole to 16 Hole Narrow D.C. Plate Dia.- 4.5mm Length - 4 Hole to 18 Hole Broad D.C. Plate Dia.- 4.5mm Length - 4 Hole to 22 Hole Small L. C. D.C. Plate Dia.- 3.5mm Length - 4 Hole to 16 Hole Narrow L.C.D.C. Plate Dia.- 4.5mm Length - 4 Hole to 18 Hole Broad L.C..D.C. Plate Dia.- 4.5mm Length - 4 Hole to 22 Hole Small T- Plate Dia.- 3.5mm Length - 2 Hole to 10 Hole Oblique T- Plate Dia.- 3.5mm Length - 2 Hole to 10 Hole Left/Right Reconstruction Plate Dia.- 3.5mm,4.5mm Length - 4 Hole to 30 Hole Ellis Plate Dia.- 3.5mm Length - 2 Hole to 10 Hole Sherman Y Plate Dia.- 3.5mm Length - 2 Hole to 12 Hole Semi Tubular Plate Dia.- 4.5mm Length - 4 Hole to 16 Hole One Third Tubular Plate Dia.- 3.5mm Length - 3 Hole to 16 Hole Cloverleaf Plate Dia.- 4.5mm Length - 3 Hole to 12 Hole T-Buttress Plate Dia.- 4.5mm Length - 3 Hole to 16 Hole L-Buttress Plate Dia.- 4.5mm Length - 3 Hole to 16 Hole, Left/Right Condylar Buttress Plate Dia.- 4.5mm Length - 4 Hole to 16 Hole, Left/Right Lateral Tibia Plate Dia.- 4.5mm Length - 4 Hole to 16 Hole, Left/Right D.H.S Plate Dia.- 120° to 150° DC Hole/ Round Hole Long Barrel/ Short Barrel Length - 4 Hole to 16 Hole 95 Degree DCS Plate Dia.- 95° Length - 4 Hole to 16 Hole Lateral Tibia Locking Plate Length - 3 Hole to 16 Hole, Left/Right Anatomical Proximal Tibia Locking Plate Length - 3 Hole to 16 Hole, Left/Right Distal Femour Locking Plate Length - 5 Hole to 16 Hole, Left/Right Proximal Femour Locking Plate Length - 3 Hole to 16 Hole, Left/Right Reconstruction Locking Plate Length - 3 Hole to 20 Hole Phillos Locking Plate Length - 3 Hole to 12 Hole Clavical Hook Locking pLate Length - 4 Hole to 8 Hole, Left/Right Clavical Medial Locking Plate Length - 4 Hole to 8 Hole, Left/Right Superior Anterior Clavical Locking Plate Length - 4 Hole to 8 Hole, Left/Right Oblique T- Locking Plate Length - 3 Hole to 10 Hole Left/Right Small T- Locking plate Length - 3 Hole to 12 Hole T-Buttress Locking Plate Length - 3 Hole to 12 Hole L- Buttress Locking Plate Length - 3 Hole to 12 Hole Left/Right Small Locking Plate Length - 4 Hole to 12 Hole Narrow Locking Plate Length - 4 Hole to 16 Hole Broad Locking Plate Length - 4 Hole to 18 Hole Proximal HUmerus Locking Plate Length - 3 Hole to 10 Hole Distal Tibial Medial Locking Plate Length - 3 Hole to 14 Hole Left/Right Distal Medial Locking Plate Length - 3 Hole to 14 Hole Left/Right Distal Tibia Locking Plate Length - 3 Hole to 14 Hole Left/Right Distal Humerus Dorsolateral With Support Locking Plate Length - 3 Hole to 14 Hole Left/Right Distal Humerus Dorsolateral Without Support Locking Plate Length - 3 Hole to 14 Hole Left/Right Distal Medial Humerus Metaphyseal Locking Plate Length - 3 Hole to 14 Hole Left/Right Posterior Medial Proximal Tibia Locking Plate Length - 2 Hole to 10 Hole Proximal Medial Tibia Locking Plate Length - 4 Hole to 10 Hole Calcanel Locking Plate Length- Small,Medium,Large Pilon Locking Plate Length - 3 Hole to 10 Hole Volar Distal Radius Locking Plate Length - 3 Hole to 10 Hole Left/Right Olecranon Locking plate Length - 3 Hole to 10 Hole Left/Right Osteotomy Locking Plate Length - 3 Hole to 10 Hole Osteotomy Locking Block Length - 12mm to 18mm Proximal Femur Locking Plate Length - 3 Hole to 12 Hole Left/Right Lateral Proximal Tibia Locking Plate Length - 4 Hole to 16 Hole Left/Right Lateral Distal Tibia Locking Plate Length - 4 Hole to 16 Hole Left/Right Medial Proximal Tibia Locking Plate Length - 4 Hole to 16 Hole Left/Right Locking Distal Fibula Plate Length - 4 Hole to 10 Hole Left/Right Mini Plate With Gap Dia.- 1.5mm to 2.5mm Length - 2 Hole to 8 Hole Mini Continues Plate Dia.- 1.5mm to 2.5mm Length - 2 Hole to 50 Hole Mini T Plate Dia.- 1.5mm to 2.5mm Length - 2 Hole to 6 Hole Mini L Plate Dia.- 1.5mm to 2.5mm Length - 2 Hole to 6 Hole Mini Y Plate Dia.- 1.5mm to 2.5mm Length - Small,Big,Double Mini X Plate Dia.- 1.5mm to 2.5mm Length - 4 Hole Mini Z Plate Dia.- 1.5mm to 2.5mm Length - 4 Hole Mini Curved Plate Dia.- 1.5mm to 2.5mm Length - 4 Hole,6 Hole Mini Angular Plate Dia.- 1.5mm to 2.5mm Length - 4 Hole,6 Hole Mini Orbita Plate Dia.- 1.5mm to 2.5mm Length - 2 Hole to 6 Hole Mini Nose Plate Dia.- 1.5mm to 2.5mm H Shape,Y shape
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	Mini Chin Plate Dia.- 1.5mm to 2.5mm Chin Shape Mini H plate Dia.- 1.5mm to 2.5mm Length - 4 Hole to 10 Hole Eight Plate Small/medium/Large Suture Disk Conical and 2 Hole Shelflife:not applicable Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Not Applicable
5	Generic Name:Nails Model No.:NIL Intended Use:Nails are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device. Class of medical device:Class C Material of construction:Stainless Steel 316L Dimension(if any):INTERLOCKING NAIL FOR TIBIA (TUBE) 8 MM = 280 TO 380 MM 9 MM = 280 TO 380 MM 10 MM = 280 TO 380 MM 11 MM = 280 TO 380 MM SOLID TIBIA NAIL 8 MM = 280 TO 380 MM 9 MM = 280 TO 380 MM 10 MM = 280 TO 380 MM DISTAL TIBIA NAIL - CANNULATED 8 MM = 280 TO 380 MM 9 MM = 280 TO 380 MM 10 MM = 280 TO 380 MM 11 MM = 280 TO 380 MM GUNDRILL TIBIA NAIL 8 MM = 280 TO 380 MM 9 MM = 280 TO 380 MM 10 MM = 280 TO 380 MM 11 MM = 280 TO 380 MM S.T.NAIL - 45 8 MM = 280 TO 380 MM 9 MM = 280 TO 380 MM 10 MM = 280 TO 380 MM INTERLOCKING NAIL FOR FEMUR 9 MM = 360 TO 440 MM 10 MM = 360 TO 440 MM 11 MM = 360 TO 440 MM 12 MM = 360 TO 440 MM SOLID FEMUR NAIL 9 MM = 360 TO 440 MM 10 MM = 360 TO 440 MM 11 MM = 360 TO 440 MM 12 MM = 360 TO 440 MM RE-CON NAIL - 135 (RIGHT) 9 MM = 340 TO 440 MM 10 MM = 340 TO 440 MM 11 MM = 340 TO 440 MM RE-CON NAIL - 135 (LEFT) 9 MM = 340 TO 440 MM 10 MM = 340 TO 440 MM 11 MM = 340 TO 440 MM SUPRACONDYLER NAIL 10 MM = 150,200,250 MM 11 MM = 150,200,250 MM 12 MM = 150,200,250 MM GUNDRILL FEMUR NAIL 9 MM = 360 TO 440 MM 10 MM = 360 TO 440 MM 11 MM = 360 TO 440 MM 12 MM = 360 TO 440 MM RETROGRADE FEMORAL NAIL (SOILD) 8 MM = 280 - 380 MM 9 MM = 280 - 380 MM 10 MM = 280 - 380 MM PROXIMAL FEMUR NAIL - SHORT-130 9 MM = 250MM 10 MM = 250MM 11 MM = 250MM 12 MM = 250MM PROXIMAL FEMUR NAIL - SHORT-135 9 MM = 250MM 10 MM = 250MM 11 MM = 250MM 12 MM = 250MM LONG P.F.NAIL - 130 - RIGHT 9 MM = 340 TO 440 MM 10 MM = 340 TO 440 MM 11 MM = 340 TO 440 MM LONG P.F.NAIL - 135 - RIGHT 9 MM = 340 TO 440 MM 10 MM = 340 TO 440 MM 11 MM = 340 TO 440 MM LONG P.F.NAIL - 130 - LEFT 9 MM = 340 TO 440 MM 10 MM = 340 TO 440 MM 11 MM = 340 TO 440 MM LONG P.F.NAIL - 135 - LEFT 9 MM = 340 TO 440 MM 10 MM = 340 TO 440 MM 11 MM = 340 TO 440 MM HUMERUS NAIL 6 MM = 200 TO 300 MM 7 MM = 200 TO 300 MM 8 MM = 200 TO 300 MM 9 MM = 200 TO 300 MM KNEE ARTHRODESIS NAIL 9 MM = UPTO 800 MM 10 MM = UPTO 800 MM 11 MM = UPTO 800 MM 12 MM = UPTO 800 MM ENDER'S NAIL 3.5 MM = 200 TO 300 MM 4.0 MM = 280 TO 380 MM 4.5 MM = 360 TO 440 MM Shelflife:not applicable Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Not Applicable

6	Generic Name:Nails Model No.:NIL Intended Use:Nails are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device. Class of medical device:Class C Material of construction:Titanium Dimension(if any):INTERLOCKING NAIL FOR TIBIA (TUBE) 8 MM = 280 TO 380 MM 9 MM = 280 TO 380 MM 10 MM = 280 TO 380 MM 11 MM = 280 TO 380 MM SOLID TIBIA NAIL 8 MM = 280 TO 380 MM 9 MM = 280 TO 380 MM 10 MM = 280 TO 380 MM 11 MM = 280 TO 380 MM DISTAL TIBIA NAIL - CANNULATED 8 MM = 280 TO 380 MM 9 MM = 280 TO 380 MM 10 MM = 280 TO 380 MM 11 MM = 280 TO 380 MM GUNDRILL TIBIA NAIL 8 MM = 280 TO 380 MM 9 MM = 280 TO 380 MM 10 MM = 280 TO 380 MM 11 MM = 280 TO 380 MM S.T.NAIL - 45 8 MM = 280 TO 380 MM 9 MM = 280 TO 380 MM 10 MM = 280 TO 380 MM INTERLOCKING NAIL FOR FEMUR 9 MM = 360 TO 440 MM 10 MM = 360 TO 440 MM 11 MM = 360 TO 440 MM 12 MM = 360 TO 440 MM SOLID FEMUR NAIL 9 MM = 360 TO 440 MM 10 MM = 360 TO 440 MM 11 MM = 360 TO 440 MM 12 MM = 360 TO 440 MM RE-CON NAIL - 135 (RIGHT) 9 MM = 340 TO 440 MM 10 MM = 340 TO 440 MM 11 MM = 340 TO 440 MM RE-CON NAIL - 135 (LEFT) 9 MM = 340 TO 440 MM 10 MM = 340 TO 440 MM 11 MM = 340 TO 440 MM SUPRACONDYLER NAIL 10 MM = 150,200,250 MM 11 MM = 150,200,250 MM 12 MM = 150,200,250 MM GUNDRILL FEMUR NAIL 9 MM = 360 TO 440 MM 10 MM = 360 TO 440 MM 11 MM = 360 TO 440 MM 12 MM = 360 TO 440 MM RETROGRADE FEMORAL NAIL (SOILD) 8 MM = 280 - 380 MM 9 MM = 280 - 380 MM 10 MM = 280 - 380 MM 11 MM = 250MM 12 MM = 250MM PROXIMAL FEMUR NAIL - SHORT-130 9 MM = 250MM 10 MM = 250MM 11 MM = 250MM 12 MM = 250MM PROXIMAL FEMUR NAIL - SHORT-135 9 MM = 250MM 10 MM = 250MM 11 MM = 250MM 12 MM = 250MM LONG P.F.NAIL - 130 - RIGHT 9 MM = 340 TO 440 MM 10 MM = 340 TO 440 MM 11 MM = 340 TO 440 MM LONG P.F.NAIL - 135 - RIGHT 9 MM = 340 TO 440 MM 10 MM = 340 TO 440 MM 11 MM = 340 TO 440 MM LONG P.F.NAIL - 130 - LEFT 9 MM = 340 TO 440 MM 10 MM = 340 TO 440 MM 11 MM = 340 TO 440 MM LONG P.F.NAIL - 135 - LEFT 9 MM = 340 TO 440 MM 10 MM = 340 TO 440 MM 11 MM = 340 TO 440 MM HUMERUS NAIL 6 MM = 200 TO 300 MM 7 MM = 200 TO 300 MM 8 MM = 200 TO 300 MM 9 MM = 200 TO 300 MM KNEE ARTHRODESIS NAIL 9 MM = UPTO 800 MM 10 MM = UPTO 800 MM 11 MM = UPTO 800 MM 12 MM = UPTO 800 MM ENDER'S NAIL 3.5 MM = 200 TO 300 MM 4.0 MM = 280 TO 380 MM 4.5 MM = 360 TO 440 MM Shelflife:not applicable Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Not Applicable
7	Generic Name:Spinal Implants Model No.:NIL Intended Use:Spinal implants are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device. Class of medical device:Class C Material of construction:Stainless Steel 316L Dimension(if any):Reduction Screw Dia. - 4.0mm to 7.0mm Length - 25mm to 60mm Poly Axial Screw Dia. - 4.0mm to 7.0mm Length - 25mm to 60mm Mono Axial Screw Dia. - 4.0mm to 7.0mm Length - 25mm to 60mm Hook Epra Hook,Supra Hook,Pedicle Hook Twin Connector Connecting Rod Dia.- 3.0mm to 5.5mm Length 50mm to 500mm Cervical Z locking Plate Cervical Cage Length - 12mm to 18mm Expandable Cage Eco Cage Dia.- 10mm to 24mm Size 20mm to 100mm Shelflife:not applicable Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Not Applicable

8	Generic Name:Spinal Implants Model No.:NIL Intended Use:Spinal implants are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device. Class of medical device:Class C Material of construction:Titanium Dimension(if any):Reduction Screw Dia. - 4.0mm to 7.0mm Length - 25mm to 60mm Poly Axial Screw Dia. - 4.0mm to 7.0mm Length - 25mm to 60mm Mono Axial Screw Dia. - 4.0mm to 7.0mm Length - 25mm to 60mm Hook Epra Hook,Supra Hook,Pedicle Hook Twin Connector Connecting Rod Dia.- 3.0mm to 5.5mm Length 50mm to 500mm Cervical Z locking Plate Cervical Cage Length - 12mm to 18mm Expandable Cage Eco Cage Dia.- 10mm to 24mm Size 20mm to 100mm Shelflife:not applicable Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Not Applicable
9	Generic Name:Wire and Pins Model No.:NIL Intended Use:Wire and pins are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device. Class of medical device:Class C Material of construction:Stainless Steel 316L Dimension(if any):Krishner Wire Dia.- 1.0mm to 3.5mm Length - 50mm to 400mm Specification - Threaded Tip/ Trocar Tip Stienman Pin Dia.- 3.0mm to 6.0mm Length - 100mm to 300mm Schanz Screw Dia.- 2.0mm to 6.0mm Length - 50mm to 400mm Denham Pin Dia.- 3.0mm to 6.0mm Length - 100mm to 300mm Shelflife:not applicable Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Not Applicable
10	Generic Name:Wire and Pins Model No.:NIL Intended Use:Wire and pins are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device. Class of medical device:Class C Material of construction:Titanium Dimension(if any):Krishner Wire Dia.- 1.0mm to 3.5mm Length - 50mm to 400mm Specification - Threaded Tip/ Trocar Tip Stienman Pin Dia.- 3.0mm to 6.0mm Length - 100mm to 300mm Schanz Screw Dia.- 2.0mm to 6.0mm Length - 50mm to 400mm Denham Pin Dia.- 3.0mm to 6.0mm Length - 100mm to 300mm Shelflife:not applicable Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Not Applicable

Place:

Date12-Jul-19

Central Licensing Authority