



सत्यमेव जयते

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/2020/000050

1. M/s MATRIX MEDITEC PVT. LTD., 34, SAKET INDUSTRIAL ESTATE, VILLAGE - MORAIYA, SANAND, --, Gujarat (India) - 382213 Telephone No.: 7965218222 FAX: 7965218222 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s Matrix Meditec Pvt. Ltd., 34, SAKET INDUSTRIAL ESTATE, VILLAGE - MORAIYA, TAL. - SANAND, Ahmedabad, Gujarat (India) - 382213 Telephone No.: 7965218222 FAX: 7930080234

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)
-------	----------------------

सत्यमेव जयते

1	<p>Generic Name:Bone Screws</p> <p>Model No.:NIL</p> <p>Intended Use:Orthopedic Implants are intended to be used for the internal fixation of bone fractures and bone reconstruction. Bone screws are intended for long and small bone fracture fixation. Metallic bone screws are internal support, which temporarily align the fracture until bony fusion occurs.</p> <p>Class of medical device:Class C</p> <p>Material of construction:Stainless Steel</p> <p>Dimension(if any):Locking Head Screw (LHS) 2.4 mm, Locking Head Screw (LHS) 2.7 mm, Locking Head Screw (LHS) 3.5 mm, Locking Head Screw (LHS) 5.0 mm, Cancellous Locking Head Screw 3.5mm, Cancellous Locking Head Screw 5.0mm, Cancellous Locking Head Screw 6.5mm & 16 mm thread, Cancellous Locking Head Screw 6.5mm & 32 mm thread, Cancellous Locking Head Screw 6.5mm & full thread, Cancellous Locking Head Screw 4.0mm & short thread, Cancellous Locking Head Screw 4.0 mm & full thread, Cannulated cancellous Locking Head Screw 6.5mm & 16 mm thread, Cannulated cancellous Locking Head Screw 6.5mm & 32 mm thread, Cannulated cancellous Locking Head Screw 4.0 mm & full thread, Cannulated cancellous Locking Head Screw 4.0 mm & short thread, Cortex Screw 2.7mm, Cortex Screw 2.7mm & self tapping, Cortex Screw 3.5mm, Cortex Screw 3.5mm & self tapping, Cortex Screw 4.5mm, Cortex Screw 4.5mm & self tapping, Malleolar Screw 4.5mm, Cancellous Screw 4.0mm & short thread, Cancellous Screw 4.0mm & full thread, Cancellous Screw 6.5 mm & 16 mm thread, Cancellous Screw 6.5 mm & 32 mm thread, Cancellous Screw 6.5 mm & full thread, Cannulated Cancellous Screw 4.0mm & short thread, Cannulated Cancellous Screw 4.0mm & full thread, Cannulated Cancellous Screw 6.5mm & 16 mm thread, Cannulated Cancellous Screw 6.5 mm & 32 mm thread, Cannulated Cancellous Screw 6.5mm & full thread, Herbert Cannulated Screw, DHS Screw 12.5mm, Schanz Screw with self tapping, Schanz Screw, Locking Bolt with Trocar Tip, Lag Screw for PFN</p> <p>Shelflife:Non-sterile - Nil & Sterile - 5 years</p> <p>Sterile or Non sterile:Both</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):NIL</p>
---	---

2	<p>Generic Name:Bone Screws</p> <p>Model No.:NIL</p> <p>Intended Use:Orthopedic Implants are intended to be used for the internal fixation of bone fractures and bone reconstruction. Bone screws are intended for long and small bone fracture fixation. Metallic bone screws are internal support, which temporarily align the fracture until bony fusion occurs.</p> <p>Class of medical device:Class C</p> <p>Material of construction:Titanium</p> <p>Dimension(if any):Locking Head Screw (LHS) 2.4 mm, Locking Head Screw (LHS) 2.7 mm, Locking Head Screw (LHS) 3.5 mm, Locking Head Screw (LHS) 5.0 mm, Cancellous Locking Head Screw 3.5mm, Cancellous Locking Head Screw 5.0mm, Cancellous Locking Head Screw 6.5mm & 16 mm thread, Cancellous Locking Head Screw 6.5mm & 32 mm thread, Cancellous Locking Head Screw 6.5mm & full thread, Cancellous Locking Head Screw 4.0mm & short thread, Cancellous Locking Head Screw 4.0 mm & full thread, Cannulated cancellous Locking Head Screw 6.5mm & 16 mm thread, Cannulated cancellous Locking Head Screw 6.5mm & 32 mm thread, Cannulated cancellous Locking Head Screw 4.0 mm & full thread, Cannulated cancellous Locking Head Screw 4.0 mm & short thread, Cortex Screw 2.7mm, Cortex Screw 2.7mm & self tapping, Cortex Screw 3.5mm, Cortex Screw 3.5mm & self tapping, Cortex Screw 4.5mm, Cortex Screw 4.5mm & self tapping, Malleolar Screw 4.5mm, Cancellous Screw 4.0mm & short thread, Cancellous Screw 4.0mm & full thread, Cancellous Screw 6.5 mm & 16 mm thread, Cancellous Screw 6.5 mm & 32 mm thread, Cancellous Screw 6.5 mm & full thread, Cannulated Cancellous Screw 4.0mm & short thread, Cannulated Cancellous Screw 4.0mm & full thread, Cannulated Cancellous Screw 6.5mm & 16 mm thread, Cannulated Cancellous Screw 6.5 mm & 32 mm thread, Cannulated Cancellous Screw 6.5mm & full thread, Herbert Cannulated Screw, DHS Screw 12.5mm, Schanz Screw with self tapping, Schanz Screw, Locking Bolt with Trocar Tip, Lag Screw for PFN</p> <p>Shelflife:Non-sterile - Nil & Sterile - 5 years</p> <p>Sterile or Non sterile:Both</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):NIL</p>
---	--

3	<p>Generic Name:Bone Plates</p> <p>Model No.:NIL</p> <p>Intended Use:Orthopedic Implants are intended to be used for the internal fixation of bone fractures and bone reconstruction. The use of plate is indicated: - When anatomical alignment must be restored accurately. - Where the use of screws alone is inadequate. - When load sharing may be achieved with confidence. If this cannot be guaranteed, then a bone graft may be added at the site of any deficit. The areas of the body where the conditions described above arise commonly are: - Around joints – failure to restore a joint surface to its normal shape may lead to osteoarthritis because of uneven wear of the joint surfaces. - In the bone of the forearm which rotates about each other. - On the pelvis especially around the acetabulum - On the face and jaw.</p> <p>Class of medical device:Class C</p> <p>Material of construction:Stainless Steel</p> <p>Dimension(if any):Locking Plates - LCP Clavicle Hook Plate 3.5mm, LCP Superior Anterior Clavicle 3.5 mm, LCP Superior Anterior Clavicle 3.5mm With Lateral Extension, LCP Proximal Humerus 3.5mm, LCP Proximal Humerus Long Philos 3.5mm, LCP Proximal Humerus Philos 3.5mm, LCP Periarticular Proximal Humerus Plate 3.5mm, LCP Medial Distal Humerus 3.5mm, LCP Posterolateral Distal Humerus 3.5mm With Support, LCP Posterolateral Distal Humerus 3.5mm Without Support, LCP Extra-articular Distal Humerus 3.5mm, LCP Olecranon 3.5mm, LCP T-Plate 3.5mm R Angle, LCP Distal Radius Plate 2.4mm Extraarticular Head 04 Hole, LCP Distal Radius Plate 2.4mm Extraarticular Head 05 Hole, LCP Distal Radius Plate 2.4mm Head 05 Hole, LCP Distal Radius Plate 2.4mm Straight, LCP Distal Radius Plate 2.4mm Extra Long Head 04 Hole, LCP Distal Radius L Plate 2.4mm Head 02 Hole, LCP Distal Radius L Plate 2.4 mm Head 03 Hole, LCP Distal Radius L Plate 3.5mm Oblique Angle Head 03 Hole, LCP Distal Radius T Plate 2.4mm Head 03 Hole, LCP Distal Radius T Plate 3.5mm Narrow Right Angled Head 03 holes, LCP Distal Radius T Plate 3.5mm Small Right Angled Head 03 holes, LCP Distal Radius T Plate 3.5mm Small Right Angled Head 04 holes, LCP T-Plate 3.5mm, Oblique, LCP Distal Radius Plate 2.4mm, LCP Distal Radius Variable Angle Plate 2.4mm, LCP DCS 95°,LCP DHS, LCP Pediatric Hip, LCP Proximal Femur 4.5mm, LCP Proximal Femur 4.5mm (VT), LCP Distal Femur 4.5 mm, LCP Proximal Femur Hook 4.5mm, LCP Proximal Lateral Tibia 4.5mm, LCP Periarticular Proximal Lateral Tibia, LCP Medial Proximal Tibia 3.5mm, LCP Proximal Tibia Plate 4.5mm, LCP Posterior Medial Proximal Tibial 3.5mm, LCP Medial Distal Tibia 3.5mm Without Tab, LCP Medial Distal Tibia 4.5 mm, Medial High Tibia Osteotomy Plate 4.5mm (Tomofix), LCP Anterolateral Distal Tibia 3.5mm, LCP L-Buttress 4.5mm, LCP T-Plate 4.5mm, LCP T-Buttress 4.5mm, LCP Distal Fibula 3.5mm, LCP 3.5mm, LCP Narrow 4.5mm, LCP Broad 4.5mm, LCP Reconstruction 3.5mm, LCP Reconstruction 3.5mm With Combi Hole, LCP Reconstruction 4.5mm, LCP Metaphyseal, LCP Pilon 3.5mm, LCP Cloverleaf 3.5mm, Locking Calcaneal Plate, LCP C Plate Foot & Ankle Plates - Lepidus Plate, MP Mini MTP Locking Plate, Mini Y Small Locking Plate, MP Ankle L Plate Oblique Angle, MP Ankle Straight Plate, MP Ankle YPlate with Bar, MP Calcaneal Plate, MP Midfoot C Plate, MP Midfoot TMT Plate, MP Mini Link Plate, MP First MTP Fusion Plate, MP Mini Universal X Plate, MP Mini X-Plate, MP Rhomboid Plate, MP Stick Plate, MP Universal X Plate Non-locking Plates - Dynamic Compression Plate (DCP) 3.5mm, Narrow Dynamic Compression Plate (DCP) 4.5mm, Broad Dynamic Compression Plate (DCP) 4.5mm, Limited Contact Dynamic Compression Plate (LC-DCP) 3.5mm, Narrow Limited Contact Dynamic Compression Plate (LC-DCP) 4.5mm, Broad Limited Contact Dynamic Compression Plate (LC-DCP) 4.5mm, LButtress Plate 4.5mm, One Third Tubular Plate 3.5mm, Semi Tubular Plates, Reconstruction Plate 3.5 mm, Reconstruction Y Plate 3.5 mm, Reconstruction Plate 4.5mm, Pelvic Reconstruction J-Plate 3.5 mm, Pelvic Reconstruction Plate 3.5mm Curved, Pelvic Reconstruction Plate 3.5mm Straight, Condylar Plate 95° (Angled Blade Plate), T- Plate 3.5mm R Angle, T-Plate 3.5mm Oblique Angle, TPlate</p>
---	--

	4.5mm, T-Buttress Plate 4.5mm, Cloverleaf Plate, DCS Plate 95°, Lateral Tibial Head Buttress Plate 4.5mm, DHS Plate DC Hole, DHS Plate Round Hole Shelflife:Non-sterile - Nil & Sterile - 5 years Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):NIL
--	--



Generic Name: Bone Plates

Model No.: NIL

Intended Use: Orthopedic Implants are intended to be used for the internal fixation of bone fractures and bone reconstruction. The use of plate is indicated: - When anatomical alignment must be restored accurately. - Where the use of screws alone is inadequate. - When load sharing may be achieved with confidence. If this cannot be guaranteed, then a bone graft may be added at the site of any deficit. The areas of the body where the conditions described above arise commonly are: - Around joints – failure to restore a joint surface to its normal shape may lead to osteoarthritis because of uneven wear of the joint surfaces. - In the bone of the forearm which rotates about each other. - On the pelvis especially around the acetabulum - On the face and jaw.

Class of medical device: Class C

Material of construction: Titanium

Dimension(if any): Locking Plates - LCP Clavicle Hook Plate 3.5mm, LCP Superior Anterior Clavicle 3.5 mm, LCP Superior Anterior Clavicle 3.5mm With Lateral Extension, LCP Proximal Humerus 3.5mm, LCP Proximal Humerus Long Philos 3.5mm, LCP Proximal Humerus Philos 3.5mm, LCP Periarticular Proximal Humerus Plate 3.5mm, LCP Medial Distal Humerus 3.5mm, LCP Posterolateral Distal Humerus 3.5mm With Support, LCP Posterolateral Distal Humerus 3.5mm Without Support, LCP Extra-articular Distal Humerus 3.5mm, LCP Olecranon 3.5mm, LCP T-Plate 3.5mm R Angle, LCP Distal Radius Plate 2.4mm Extraarticular Head 04 Hole, LCP Distal Radius Plate 2.4mm Extraarticular Head 05 Hole, LCP Distal Radius Plate 2.4mm Head 05 Hole, LCP Distal Radius Plate 2.4mm Straight, LCP Distal Radius Plate 2.4mm Extra Long Head 04 Hole, LCP Distal Radius L Plate 2.4mm Head 02 Hole, LCP Distal Radius L Plate 2.4 mm Head 03 Hole, LCP Distal Radius L Plate 3.5mm Oblique Angle Head 03 Hole, LCP Distal Radius T Plate 2.4mm Head 03 Hole, LCP Distal Radius T Plate 3.5mm Narrow Right Angled Head 03 holes, LCP Distal Radius T Plate 3.5mm Small Right Angled Head 03 holes, LCP Distal Radius T Plate 3.5mm Small Right Angled Head 04 holes, LCP T-Plate 3.5mm, Oblique, LCP Distal Radius Plate 2.4mm, LCP Distal Radius Variable Angle Plate 2.4mm, LCP DCS 95°, LCP DHS, LCP Pediatric Hip, LCP Proximal Femur 4.5mm, LCP Proximal Femur 4.5mm (VT), LCP Distal Femur 4.5 mm, LCP Proximal Femur Hook 4.5mm, LCP Proximal Lateral Tibia 4.5mm, LCP Periarticular Proximal Lateral Tibia, LCP Medial Proximal Tibia 3.5mm, LCP Proximal Tibia Plate 4.5mm, LCP Posterior Medial Proximal Tibial 3.5mm, LCP Medial Distal Tibia 3.5mm Without Tab, LCP Medial Distal Tibia 4.5 mm, Medial High Tibia Osteotomy Plate 4.5mm (Tomofix), LCP Anterolateral Distal Tibia 3.5mm, LCP L-Buttress 4.5mm, LCP T-Plate 4.5mm, LCP T-Buttress 4.5mm, LCP Distal Fibula 3.5mm, LCP 3.5mm, LCP Narrow 4.5mm, LCP Broad 4.5mm, LCP Reconstruction 3.5mm, LCP Reconstruction 3.5mm With Combi Hole, LCP Reconstruction 4.5mm, LCP Metaphyseal, LCP Pilon 3.5mm, LCP Cloverleaf 3.5mm, Locking Calcaneal Plate, LCP C Plate Foot & Ankle Plates - Lepidus Plate, MP Mini MTP Locking Plate, Mini Y Small Locking Plate, MP Ankle L Plate Oblique Angle, MP Ankle Straight Plate, MP Ankle Y Plate with Bar, MP Calcaneal Plate, MP Midfoot C Plate, MP Midfoot TMT Plate, MP Mini Link Plate, MP First MTP Fusion Plate, MP Mini Universal X Plate, MP Mini X-Plate, MP Rhomboid Plate, MP Stick Plate, MP Universal X Plate Non-locking Plates - Dynamic Compression Plate (DCP) 3.5mm, Narrow Dynamic Compression Plate (DCP) 4.5mm, Broad Dynamic Compression Plate (DCP) 4.5mm, Limited Contact Dynamic Compression Plate (LC-DCP) 3.5mm, Narrow Limited Contact Dynamic Compression Plate (LC-DCP) 4.5mm, Broad Limited Contact Dynamic Compression Plate (LC-DCP) 4.5mm, LButtress Plate 4.5mm, One Third Tubular Plate 3.5mm, Semi Tubular Plates, Reconstruction Plate 3.5 mm, Reconstruction Y Plate 3.5 mm, Reconstruction Plate 4.5mm, Pelvic Reconstruction J-Plate 3.5 mm, Pelvic Reconstruction Plate 3.5mm Curved, Pelvic Reconstruction Plate 3.5mm Straight, Condylar Plate 95° (Angled Blade Plate), T- Plate 3.5mm R Angle, T-Plate 3.5mm Oblique Angle, TPlate

	<p>4.5mm, T-Buttress Plate 4.5mm, Cloverleaf Plate, DCS Plate 95°, Lateral Tibial Head Buttress Plate 4.5mm, DHS Plate DC Hole, DHS Plate Round Hole</p> <p>Shelflife:Non-sterile - Nil & Sterile - 5 years</p> <p>Sterile or Non sterile:Both</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):NIL</p>
5	<p>Generic Name:Pins, Wires, Washers & Spacers</p> <p>Model No.:NIL</p> <p>Intended Use:Pins: Pins are used in fixation of fractures where minimal bone and soft tissue damage are involved. Pins provide provisional fixation leaving room for additional hardware placement. The provisional fixation is planned to avoid faulty permanent fixation. Depending on the diameter, pins may also be used as guidewires for cannulated screw fixation. Wires: Wires are used in the fixation of fractures in which loading is minimal. Wires are easier to bend, so, are supplemented with other immobilization devices where necessary. Pin or wire fixation is mostly used for fractures of the Phalanges, Metacarpals, Metatarsals, Proximal Humerus and Distal Humerus. Washers: Washers are to function with screws to prevent the screw head from breaking through the cortex of the bone by providing additional surface area during screw placement. Spacers: To reduce the plate-to-bone contact to a minimum, screw a spacer in the plate before positioning the plate. The spacer ensures that a distance of 2 mm will be maintained between the plates and the bone when the screws are later inserted. The spacer can be removed after setting the locking screws.</p> <p>Class of medical device:Class C</p> <p>Material of construction:Stainless Steel</p> <p>Dimension(if any):Denham Pin with Thread, Steinmann Pin with Trocar Tip, Threaded Tapper Pin, Kirschner Wire with Double Tip, Kirschner Wire with Single Tip, Kirschner Wire with Threaded Tip, Washers, Spacers, Wire mount</p> <p>Shelflife:Non-sterile - Nil & Sterile - 5 years</p> <p>Sterile or Non sterile:Both</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):NIL</p>

6	<p>Generic Name:Pins, Wires, Washers & Spacers</p> <p>Model No.:NIL</p> <p>Intended Use:Pins: Pins are used in fixation of fractures where minimal bone and soft tissue damage are involved. Pins provide provisional fixation leaving room for additional hardware placement. The provisional fixation is planned to avoid faulty permanent fixation. Depending on the diameter, pins may also be used as guidewires for cannulated screw fixation. Wires: Wires are used in the fixation of fractures in which loading is minimal. Wires are easier to bend, so, are supplemented with other immobilization devices where necessary. Pin or wire fixation is mostly used for fractures of the Phalanges, Metacarpals, Metatarsals, Proximal Humerus and Distal Humerus. Washers: Washers are to function with screws to prevent the screw head from breaking through the cortex of the bone by providing additional surface area during screw placement. Spacers: To reduce the plate-to-bone contact to a minimum, screw a spacer in the plate before positioning the plate. The spacer ensures that a distance of 2 mm will be maintained between the plates and the bone when the screws are later inserted. The spacer can be removed after setting the locking screws.</p> <p>Class of medical device:Class C</p> <p>Material of construction:Titanium</p> <p>Dimension(if any):Denham Pin with Thread, Steinmann Pin with Trocar Tip, Threaded Tapper Pin, Kirschner Wire with Double Tip, Kirschner Wire with Single Tip, Kirschner Wire with Threaded Tip, Washers, Spacers, Wire mount</p> <p>Shelflife:Non-sterile - Nil & Sterile - 5 years</p> <p>Sterile or Non sterile:Both</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):NIL</p>
7	<p>Generic Name:Intramedullary Nails (IM Nails)</p> <p>Model No.:NIL</p> <p>Intended Use:The Intramedullary Nail System is intended for surgical management of femoral and tibial fractures including open and closed fractures, pseudarthrosis and correction osteotomy, pathologic fractures, impending pathologic fractures, tumor resections, nonunions and malunions. The hip nails may be used for basilar neck, subtrochanteric and intertrochanteric fractures. The femoral nails may be used for fractures of the femur below the hip joint including ipsilateral femur fractures, fractures proximal to a total knee arthroplasty and supracondylar fractures, including those with intraarticular extension.</p> <p>Class of medical device:Class C</p> <p>Material of construction:Stainless Steel</p> <p>Dimension(if any):Humeral Nail, Square Nail, Rush Nail, Elastic Nail, Femoral Interlocking Nail, Trochantric Femoral Interlocking Nail 130° & 135°, Short Proximal Femoral Nail 130°& 135°, Proximal Femoral Nail 130°, 135° & AR, Syrus Femoral Nail, Supra Condylar Nail, Universal Femoral Nail, Enders Nail, Tibial Upper Bend Nail, Dynamic Tibial Nail, Solid Tibial Nail, Universal Tibial Nail, MP Ankle Arthrodesis Nail, End caps</p> <p>Shelflife:Non-sterile - Nil & Sterile - 5 years</p> <p>Sterile or Non sterile:Both</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):NIL</p>

8	<p>Generic Name:Intramedullary Nails (IM Nails)</p> <p>Model No.:NIL</p> <p>Intended Use:The Intramedullary Nail System is intended for surgical management of femoral and tibial fractures including open and closed fractures, pseudarthrosis and correction osteotomy, pathologic fractures, impending pathologic fractures, tumor resections, nonunions and malunions. The hip nails may be used for basilar neck, subtrochanteric and intertrochanteric fractures. The femoral nails may be used for fractures of the femur below the hip joint including ipsilateral femur fractures, fractures proximal to a total knee arthroplasty and supracondylar fractures, including those with intraarticular extension.</p> <p>Class of medical device:Class C</p> <p>Material of construction:Titanium</p> <p>Dimension(if any):Humeral Nail, Square Nail, Rush Nail, Elastic Nail, Femoral Interlocking Nail, Trochantric Femoral Interlocking Nail 130° & 135°, Short Proximal Femoral Nail 130°& 135°, Proximal Femoral Nail 130°, 135° & AR, Syrus Femoral Nail, Supra Condylar Nail, Universal Femoral Nail, Enders Nail, Tibial Upper Bend Nail, Dynamic Tibial Nail, Solid Tibial Nail, Universal Tibial Nail, MP Ankle Arthrodesis Nail, End caps</p> <p>Shelflife:Non-sterile - Nil & Sterile - 5 years</p> <p>Sterile or Non sterile:Both</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):NIL</p>
9	<p>Generic Name:Spinal Implants</p> <p>Model No.:NIL</p> <p>Intended Use:Spinal Implants are basically indicated to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.</p> <p>Class of medical device:Class C</p> <p>Material of construction:Titanium</p> <p>Dimension(if any):Monoaxial Screw, Polyaxial Screw, Reduction Mono Screw, Reduction Poly Screw, Monoaxial Fenestrated Screw, Polyaxial Fenestrated Screw, Reduction Monoaxial Fenestrated Extended Screw, Reduction Polyaxial Fenestrated Extended Screw, Occipital Polyaxial Screw, Cervical Bone Screw 4.0mm, Cervical Self Drilling Bone Screw 4.0mm, Cervical Revision Bone Screw 4.3mm, Occifix Plate, Occipital T Plate, Cervical Plate, Pedicle Hook, Lamina Hook - Reduced Distance, Lamina Hook -Angle Blade, Lamina Hook - Narrow Blade, Lamina Hook - Wide Blade, Transverse Connector, Crosslink Connector, Parallel Connector Square, Parallel Connector Triangle, Occipital Cervical Screw Connector, Staple, Eco Cage, Expandable Eco Cage, Bullet Cage - Transforaminal Lumbar Interbody Fusion (TLIF) & Posterior Lumbar Interbody Fusion (PLIF), Kidney Cage - Transforaminal Lumbar Interbody Fusion (TLIF) & Posterior Lumbar Interbody Fusion (PLIF), Kidney Cage II - Transforaminal Lumbar Interbody Fusion (TLIF) & Posterior Lumbar Interbody Fusion (PLIF), Cervical Cage, Cervical Cage II, Anterior Cervical Fusion Cage, Plate with cage (Colliation Cage), Rod</p> <p>Shelflife:Non-sterile - Nil & Sterile - 5 years</p> <p>Sterile or Non sterile:Both</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):NIL</p>

10	<p>Generic Name:Spinal Implants</p> <p>Model No.:NIL</p> <p>Intended Use:Spinal Implants are basically indicated to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.</p> <p>Class of medical device:Class C</p> <p>Material of construction:Polyetheretherketone (PEEK)</p> <p>Dimension(if any):Monoaxial Screw, Polyaxial Screw, Reduction Mono Screw, Reduction Poly Screw, Monoaxial Fenestrated Screw, Polyaxial Fenestrated Screw, Reduction Monoaxial Fenestrated Extended Screw, Reduction Polyaxial Fenestrated Extended Screw, Occipital Polyaxial Screw, Cervical Bone Screw 4.0mm, Cervical Self Drilling Bone Screw 4.0mm, Cervical Revision Bone Screw 4.3mm, Occifix Plate, Occipital T Plate, Cervical Plate, Pedicle Hook, Lamina Hook - Reduced Distance, Lamina Hook -Angle Blade, Lamina Hook - Narrow Blade, Lamina Hook - Wide Blade, Transverse Connector, Crosslink Connector, Parallel Connector Square, Parallel Connector Triangle, Occipital Cervical Screw Connector, Staple, Eco Cage, Expandable Eco Cage, Bullet Cage - Transforaminal Lumbar Interbody Fusion (TLIF) & Posterior Lumbar Interbody Fusion (PLIF), Kidney Cage - Transforaminal Lumbar Interbody Fusion (TLIF) & Posterior Lumbar Interbody Fusion (PLIF), Kidney Cage II - Transforaminal Lumbar Interbody Fusion (TLIF) & Posterior Lumbar Interbody Fusion (PLIF), Cervical Cage, Cervical Cage II, Anterior Cervical Fusion Cage, Plate with cage (Colliation Cage), Rod</p> <p>Shelflife:Non-sterile - Nil & Sterile - 5 years</p> <p>Sterile or Non sterile:Both</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):NIL</p>
1 1	<p>Generic Name:Maxillofacial Implants</p> <p>Model No.:NIL</p> <p>Intended Use:Orthopedic Implants are intended to be used for the internal fixation of bone fractures and bone reconstruction. Maxillofacial System are implantable bone plates and bone screws for oral and maxillofacial procedures including fractures, osteotomies, orthognathic, reconstructive procedures and revisions procedures when other treatments of devices have failed. Surgical locations for device placement include fracture and reconstruction sites in the mandible, maxilla, zygomatic bone and orbital socket.</p> <p>Class of medical device:Class C</p> <p>Material of construction:Stainless Steel</p> <p>Dimension(if any):Mini Plate with Continuous Holes, Plate with Bar, L-Plate, L-Plate with Bar, L-Plate Oblique Angle, L-Plate Oblique Angle with Bar, I-Plate, X-Plate, Y-Plate, Double Y-Plate, Z-Plate, Orbita Plate, Orbita Plate with Bar, H-Plate, T-Plate, Nose H-plate, Angular Plate, Curved Plate, Mini Screw Slotted Head, Mini Screw Cross Head</p> <p>Shelflife:Non-sterile - Nil & Sterile - 5 years</p> <p>Sterile or Non sterile:Both</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):NIL</p>

12	<p>Generic Name:Maxillofacial Implants</p> <p>Model No.:NIL</p> <p>Intended Use:Orthopedic Implants are intended to be used for the internal fixation of bone fractures and bone reconstruction. Maxillofacial System are implantable bone plates and bone screws for oral and maxillofacial procedures including fractures, osteotomies, orthognathic, reconstructive procedures and revisions procedures when other treatments of devices have failed. Surgical locations for device placement include fracture and reconstruction sites in the mandible, maxilla, zygomatic bone and orbital socket.</p> <p>Class of medical device:Class C</p> <p>Material of construction:Titanium</p> <p>Dimension(if any):Mini Plate with Continuous Holes, Plate with Bar, L-Plate, L-Plate with Bar, L-Plate Oblique Angle, L-Plate Oblique Angle with Bar, I-Plate, X-Plate, Y-Plate, Double Y-Plate, Z-Plate, Orbita Plate, Orbita Plate with Bar, H-Plate, T-Plate, Nose H-plate, Angular Plate, Curved Plate, Mini Screw Slotted Head, Mini Screw Cross Head</p> <p>Shelflife:Non-sterile - Nil & Sterile - 5 years</p> <p>Sterile or Non sterile:Both</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):NIL</p>
13	<p>Generic Name:Arthroscopy Implants</p> <p>Model No.:NIL</p> <p>Intended Use:In Arthroscopy surgery, a small fiber optic telescope (arthroscope) is inserted into a joint. In order to visualize the structure within that joint, a fluid is inserted into the joint to distend it. With our implants, we assure safety and reproducibility in technically demanding surgical procedures. Our devices are designed for graft harvesting, cruciate and meniscal reconstruction and repair systems, tunnel preparation, implants as well as meniscal associated accessories.</p> <p>Class of medical device:Class C</p> <p>Material of construction:Stainless Steel</p> <p>Dimension(if any):EndoButton, Endo-Button Continuous Loop, Fixation Button Adjustable Loop, ACL Screw, Fixation Screw, Staple – U Type / Step Spike Type, Washers (Tibial Base Plates), Spiked Washers & Low Profile Cancellous Screw, Small Suture Anchor, Large Suture Anchor, Wire Spool (Suture Wire)</p> <p>Shelflife:Non-sterile - Nil & Sterile - 5 years</p> <p>Sterile or Non sterile:Both</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):NIL</p>

14	<p>Generic Name:Arthroscopy Implants</p> <p>Model No.:NIL</p> <p>Intended Use:In Arthroscopy surgery, a small fiber optic telescope (arthroscope) is inserted into a joint. In order to visualize the structure within that joint, a fluid is inserted into the joint to distend it. With our implants, we assure safety and reproducibility in technically demanding surgical procedures. Our devices are designed for graft harvesting, cruciate and meniscal reconstruction and repair systems, tunnel preparation, implants as well as meniscal associated accessories.</p> <p>Class of medical device:Class C</p> <p>Material of construction:Titanium</p> <p>Dimension(if any):EndoButton, Endo-Button Continuous Loop, Fixation Button Adjustable Loop, ACL Screw, Fixation Screw, Staple – U Type / Step Spike Type, Washers (Tibial Base Plates), Spiked Washers & Low Profile Cancellous Screw, Small Suture Anchor, Large Suture Anchor, Wire Spool (Suture Wire)</p> <p>Shelflife:Non-sterile - Nil & Sterile - 5 years</p> <p>Sterile or Non sterile:Both</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):NIL</p>
----	---

Place:

Date02-Mar-20

Central Licensing Authority

