



सत्यमेव जयते

FORM MD-5

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

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

Licence Number: MFG/MD/2023/000639

1. M/s Sigma Surgical Pvt Ltd, Plot No 13, Shreeram Industrial Estate, B/H CMC, Soni Chawl Cross Road, OdhavAhmedabad, --, Gujarat (India) - 382415 Telephone No.: 07922976132 FAX: 07922976132 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s SIGMA SURGICAL PRIVATE LIMITED, Survey No. 1636/1, Opp. Bharat Petroleum Petrol Pump, Village-Kuha, Indore Highway, Taluka-Daskroi, District-Ahmedabad 382433, Gujarat, India, Ahmedabad, Gujarat (India) - 382433 Telephone No.: 07922976132 FAX: 07922976132

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	<p>Generic Name:Clamp Model No.:NIL Intended Use:Reusable Handheld Surgical Instrument for clamping tissues or materials or bone. These include Clamp for holding pins. Class of medical device:Class A Material of construction:SS Dimension(if any):11.0 mm * 150 mm/11.0 mm*200mm/11.0mm*250mm/11.0mm*300mm/11.0mm*350mm/11.0mm*400mm/11.0mm*450mm/11.0mm*500mm/11.0mm*100mm Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>
2	<p>Generic Name:Box Wrench for Nut/Bolt Model No.:NIL Intended Use:A minimally invasive, reusable surgical instrument intended to grip, twist or turn nut & bolt. Class of medical device:Class A Material of construction:SS Dimension(if any): Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>

3	<p>Generic Name:Instrument set for external fixation system</p> <p>Model No.:NIL</p> <p>Intended Use:The instrument used for external fixation system. These include screw guide, Allen key, half pin introducer, jig for fixator, minimally invasive spine surgery access tube, access tube holding handle, hex tightener, retractor blade, light source cable, optic fiber cable.</p> <p>Class of medical device:Class A</p> <p>Material of construction:SS</p> <p>Dimension(if any):</p> <p>Shelflife:Non-Sterile (Nil) for Sterile till seal is intact.</p> <p>Sterile or Non sterile:Both</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>
4	<p>Generic Name:Instrument set for Bone Screws & Plates</p> <p>Model No.:NIL</p> <p>Intended Use:The instrument set for bone screw & plates includes Tap, Countersink shaft, Tension device Muller type, handle for quick coupling, holding clip, Dynamic Compression Plate/Limited Contact Dynamic Compression Plate neutral & load guide, bending iron for plates, bending iron for k-wires, Direct measuring device, threaded plate holder, Push pull reduction device, Tension device Muller type, Bending pin, Refractor. The product does not include orthopedic implants.</p> <p>Class of medical device:Class A</p> <p>Material of construction:SS</p> <p>Dimension(if any):280mm/300mm/150mm</p> <p>Shelflife:Non-Sterile (Nil) for Sterile till seal is intact.</p> <p>Sterile or Non sterile:Both</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>
5	<p>Generic Name:Surgical Trays</p> <p>Model No.:NIL</p> <p>Intended Use:Trays are containers intended to provide a suitable platform for containing many medical/surgical instruments and related items during a clinical procedure. They might in addition be used during reprocessing/sterilization procedures. They are noninvasive, reusable devices.</p> <p>Class of medical device:Class A</p> <p>Material of construction:SS</p> <p>Dimension(if any):</p> <p>Shelflife:Non-Sterile (Nil) for Sterile till seal is intact.</p> <p>Sterile or Non sterile:Both</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>
6	<p>Generic Name:Sleeves and its attachment</p> <p>Model No.:NIL</p> <p>Intended Use:Manual surgical instruments that aid in the placement of bone cuts when preparing site to accept the implant components. These include Sleeve for Block for Half Pin, locking sleeve.</p> <p>Class of medical device:Class A</p> <p>Material of construction:SS</p> <p>Dimension(if any):3.5mm/3.2mm/4.5mm/14.50 mm * 16.5mm/14.5mm*3.2mm/11.0mm*8.0mm/8.0mm*4.0mm/3.50mm/8.0mm*3.2mm/2.5mm</p> <p>Shelflife:Non-Sterile (Nil) for Sterile till seal is intact.</p> <p>Sterile or Non sterile:Both</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>

7	<p>Generic Name:Surgical Drill & its attachment Model No.:NIL Intended Use:The surgical drilling machine that, when rotated at an appropriate speed, will cut into bone creating a hole of the same dimension as the diameter of the bit. The attachment includes drill bit, drill guides, burr & handpiece. Class of medical device:Class B Material of construction:SS Dimension(if any):5.0mm*300mm/5.5mm*150mm/4.0mm/3.2mm/4.3mm*200mm/4.3mm*225mm/4.0mm*300mm/4.0mm*170mm/4.0mm*150mm/4.0mm*325mm/3.2mm*300mm/1.8mm/2.0mm/2.5mm/2.8mm/4.3mm/5.0mm/6mm*90mm/5mm*85mm/4mm*75mm/5.5mm*150mm/5.0mm*300mm/4.5mm*300mm/4.5mm*200mm/4.5mm*150mm/4.5mm*195mm/3.5mm*100mm/3.5mm*150mm/3.5mm*250mm/3.2mm*100mm/3.2mm*150mm/3.2mm*170mm/3.2mm*195mm/3.2mm*200mm/3.2mm*250mm/3.2mm*300mm/3.0mm*150mm/2.8mm*180mm/2.7mm*250mm/2.7mm*200mm/2.7mm*150mm/2.7mm*100mm/2.7mm*125mm/2.5mm*200mm/2.5mm*180mm/2.5mm*150mm/2.5mm*100mm/2.4mm*150mm/2.4mm*125mm/2.4mm*100mm/2.0mm*150mm/2.0mm*125mm/2.0mm*100mm/180mm*150mm/180mm*125mm/180mm*100mm/1.5mm*100mm/1.5mm*75mm/1.0mm*100mm/1.0mm*75mm Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>
8	<p>Generic Name:Surgical Screw Driver Model No.:NIL Intended Use:A metal instrument designed to impart force on another instrument. The distal end is shaped to mate with the instrument being driven into some form of tissue. The proximal end is designed to absorb & transmit an impact force. Class of medical device:Class A Material of construction:SS Dimension(if any):3.5mm/8mm/4.5mm/T15/T25/T7/T30/T10/2.0mm/2.5mm/3.0mm/5.0mm Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>
9	<p>Generic Name:Intramedullary Locking Nail Instrument Sets Model No.:NIL Intended Use:The Intramedullary locking nail instrument sets includes Awl, Tissue Protector, Nut for coupling bolt, Proximal Jig, Distal Jig, Knob, Proximal Arm for Jig, coupling bolt, measuring device, T handle, Universal Spanner, Tommy Bar, Ram, Ram Rod, Jig cover, Detachable Slide Hammer, F-Tool, Spanner Wrench, Standard Tamp, Screw Tightener, Medullary tube Polyamide. Class of medical device:Class B Material of construction:SS Dimension(if any):3.0mm Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>
10	<p>Generic Name:Depth Gauge Model No.:NIL Intended Use:Device intended to aid surgeon in determining the appropriate length retractor blade to use based on surgical site depth through a color-coded system. Class of medical device:Class A Material of construction:SS Dimension(if any):2.7mm/2.4mm Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>

11	<p>Generic Name:Reamer & its attachment Model No.:NIL Intended Use:A hand hold instrument used to enlarge. It includes pedicle reamer, reamer for cemented stem, Distal reamer for uncemented stem, adaptors for reamers & Quick Change. The product does not include orthopedic implants. Class of medical device:Class A Material of construction:SS Dimension(if any):8.5/9.0/9.5/10.0/10.5/11.0/11.5/13.0mm/Dia. 15.5mm/6mm/7mm/8mm/9mm/10mm/11mm/12mm/13mm/5mm/3mm/4mm/12.0mm/12.5mm/13.0mm/4.5mm Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>
12	<p>Generic Name:Alignment Guide Model No.:NIL Intended Use:A reusable manual surgical instrument designed to facilitate the correct orientation (alignment) of another medical device or implant during orthopedic surgery. Class of medical device:Class A Material of construction:SS Dimension(if any):3.2mm * 400mm/1.2mm*230mm/1.5mm*230mm/2.5mm*115cm Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>
13	<p>Generic Name:Pusher Model No.:NIL Intended Use:A hand-held dental instrument designed for positioning & adapting metal bands on teeth in orthodontics. Class of medical device:Class A Material of construction:SS Dimension(if any): Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>
14	<p>Generic Name:Forceps Model No.:NIL Intended Use:Forceps are used to grasp, manipulate, compress, pull or join tissue, equipment or supplies. It includes burns for radius, modified burns, martins' cartilage forceps, sequestrum forceps, reduction forceps, self-centering forceps, Fergussons Type Bone Holding forceps, Haygrooves Type Bone- Holding Forceps, Lanes Type Bone – Holding Forcep, Patella with Single Pronge, Patella Double Pronge, Patella with Eye, Rocker Forcep, Plate & Bone Holding Forcep. Class of medical device:Class A Material of construction:SS Dimension(if any): Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>
15	<p>Generic Name:Insertion and removal instruments Model No.:NIL Intended Use:Reusable surgical instruments to facilitate the manipulation, implantation and removal of various orthopedic devices during orthopedic surgeries. Class of medical device:Class A Material of construction:SS Dimension(if any):3.5mm/4.5mm/4.0mm/2.7mm/2.5mm/6.0mm/3.0mm/2.0mm/1.5mm/1.2mm/6.5mm/5.0mm/8.0mm/10.0mm/7.0mm/T15.1/T27.1/T25.1/T30/T25/T20/T15/T10/T8/T7/5.5mm Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>

16	<p>Generic Name:Orthopaedic Countersink Model No.:NIL Intended Use:The countersinks are bone profilers which are bone cutting instruments used for bone preparation to enable the placement of gingival part of components during dental procedures in the mouth. Class of medical device:Class A Material of construction:SS Dimension(if any):3.5mm/4.0mm (C.C)/4.5mm/6.5mm Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>
17	<p>Generic Name:Bender Model No.:NIL Intended Use:A reusable surgical instrument used to bend medical device, typically those for implantation to the appropriate anatomical fit. Class of medical device:Class A Material of construction:SS Dimension(if any): Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>
18	<p>Generic Name:Bone Cutter Model No.:NIL Intended Use:A surgical instrument used to cut bone to penetrate/separate bone, during orthopedic surgical procedures. Class of medical device:Class A Material of construction:SS Dimension(if any): Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>
19	<p>Generic Name:Implant Trials Model No.:NIL Intended Use:Trials are temporary sizing guides which are used by surgeons to check the size and fit of orthopaedic implants before actual implantation of device. The product does not include orthopaedic implants. Class of medical device:Class B Material of construction:SS Dimension(if any):3.5mm/4.5mm/8mm/9mm/10mm/11mm/12mm/13mm/14mm/37mm/38mm/39mm/40mm/41mm/42mm/43mm/44mm/45mm/46mm/47mm/48mm/49mm/50mm/51mm/52mm/53mm/54mm/55mm Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>

20	<p>Generic Name:External ring Fixation System Model No.:NIL Intended Use:The Ring Fixation System consists of series of external fixators intended to be used to stabilize bone segment in a broad range of indications, including fractures, joint fusion, bone transport, lengthening & angular corrections. The system includes Half Rings 5/8 Ring, Rings With Curved Extremities, Italian Femoral Arches, Arches With Holes, Threaded Rods, Telescopic Rods, PostMale/ Female, Hinges-Male/ Female/Standard, Long/Short Connection Plates, Connected Plates With Threaded Ends, Twisted/Curved Plates, Bushing Threaded Sockets, Connection Bolts, Nut, Washers, Bolt, Multiple, Wire Fixation Buckle, Blocks for Half Pins, Universal Joint, Rotational and Translational Device, Oblique Support, Set Screw, Foot Rings, Knurling post male. Implants not included. Class of medical device:Class B Material of construction:SS Dimension(if any): Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>
21	<p>Generic Name:Spinal cage system instruments Model No.:NIL Intended Use:The spinal cage system instruments are used by surgeon for spinal implants, devices or hardware, uses surgical procedures to implant titanium, titanium alloy, stainless steel, or non-metallic devices into the spine. The instrument set includes rasp for cervical disc spacer, bone graft compactor, bone tamp for cervical disc spacer, cage support block, cervical distractor pin, cutter for cage, funnel, graft, seat holder for cervical disc spacer, introducer for cervical disc spacer, left angled curette, quick change, quick change for box chisel, spreader, tap handle - quick coupling, threaded inserter for droner peek cage, tlif cage guide, tlif cage holder, tommy bar for cages, trial for droner peek/plif /radial tlif cage, Cervical Distractor, Rasp For Radial Tlif/Plif Cage, Right Angled Curette, Screw Tighter, Pin Introducer For Vertebral Distractor, Plif Cage Holder, Dura, Curette. The system does not include orthopaedic implants. Class of medical device:Class A Material of construction:SS Dimension(if any):2.0mm/3.0mm/13mm/12mm/11mm/10mm/9mm/8mm/7mm Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>
22	<p>Generic Name:Orthopedic implant impactor Model No.:NIL Intended Use:A minimally invasive surgical instrument used in arthroscopy to transmit an impact force on bone and measure the depth of impact. Class of medical device:Class A Material of construction:SS Dimension(if any): Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>
23	<p>Generic Name:Wire tensioner Model No.:NIL 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, usually as part of a system to provide corrective surgery to the spine. The product does not include orthopaedic implants. Class of medical device:Class A Material of construction:SS Dimension(if any):1.80mm Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>

24	<p>Generic Name:Rod Cutter/Reducer Model No.:NIL Intended Use:A reusable surgical instrument used to reduce or seat an implantable rod into the saddle of the implant. Class of medical device:Class A Material of construction:SS Dimension(if any): Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>
25	<p>Generic Name:Bone Tap Model No.:NIL Intended Use:A metal surgical instrument designed for cutting internal threads into bone so that the threads facilitate the insertion of bone screws. The screws anchor bone fragments, fixtures and/or other devices to the bone. The product does not include orthopaedic implants. Class of medical device:Class A Material of construction:SS Dimension(if any):4.5mm/5.5mm/6.5mm/7.5mm Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>
26	<p>Generic Name:Spinal Instrument Model No.:NIL Intended Use:The instruments used in spinal surgery. These include Bone Cutter, Bone Nibbler Single / Double Action, Bone Nibbler Single Action, Hijack Punch, Disc Punch, Chisel with Detachable Handle Gouge with fiber handle, Plate holding forcep for C1-C2 spacer, Rounger Right Angle, Sargent Rounger, Rounger Kiliner, Olecrona Rounger, Lacksell Rounger, Kerrison Punch, Rib Rasperactory, Mastroid Retractor, Kochar's Bone hook, Micro cob elevator, Elevator Cobs, Chisel with attached fiber handle, Bone Lever, Micro Curettes, Meatal Curette, Curette, Gauge, Atraumatic Micro Force, Plate holding forcep for C1-C2 spacer, Introducer for C1-C2 spacer. Class of medical device:Class A Material of construction:SS Dimension(if any): Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>
27	<p>Generic Name:Wrench Model No.:NIL Intended Use:A heavy-duty, surgical instrument with specially designed sturdy handles and gripping jaws (typically parallel) used to grip and hold an object during a surgical intervention. It has a scissors-like design with curved handles and is made of high-grade stainless steel. It is available in various sizes and the jaws (typically broad with serrations) at the working end are activated through a single pivot or a double ratio lever exchange pivot to provide greater gripping force. This is a reusable device. This include combination wrench. Class of medical device:Class A Material of construction:SS Dimension(if any): Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>

28	<p>Generic Name:Torque Wrench Model No.:NIL Intended Use:The torque wrench is used to tighten the setscrew on the connector assemblies of the implantable pulse generator and extension. Class of medical device:Class A Material of construction:SS Dimension(if any): Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>
29	<p>Generic Name:Cervical plate system instruments Model No.:NIL Intended Use:The Cervical plate system instruments is a comprehensive system of instruments for stabilization of the spine in the cervical regions. The instruments used by surgeon includes pin fixation, plate bender, supporting pin for cervical plate, Screw Tightener for Cervical Plate Screw, Knob Aligner for Cervical Lock Plate, Plate Holder for Cervical Lock Plate, Threaded Pin. The system does not include orthopedic implants. Class of medical device:Class A Material of construction:SS Dimension(if any):5.5mm Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>
30	<p>Generic Name:Cervical disc spacer instruments for Spine Model No.:NIL Intended Use:Intended to be used in cervical disc surgery. The products include Rasp for cervical disc spacer, Graft seat holder for cervical disc spacer, Bone tamp for cervical disc spacer & Lateral mass system & small anatomical system instruments. The product does not include orthopedic implants. Class of medical device:Class A Material of construction:SS Dimension(if any): Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>
31	<p>Generic Name:Pedical Screw Instruments Model No.:NIL Intended Use:The instruments include rocker, Tap breaker, Persuader, Sound, Quick Change. These instruments used to aid surgeon in placing pedical screw in spinal fusion surgery. Class of medical device:Class A Material of construction:SS Dimension(if any): Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>
32	<p>Generic Name:Surgical Probe Model No.:NIL Intended Use:It includes curved/straight probe, thoracic probe, Depuy Probe Curved. Class of medical device:Class A Material of construction:SS Dimension(if any): Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>

33	<p>Generic Name:Instrument system for bipolar hip system Model No.:NIL Intended Use:The instrument system for bipolar hip system used in surgical procedure includes Advanced Muller Rasp handle for cemented stem, Long scoop for Hip for cemented stem, Rasp for cemented stem, Insertor for cemented stem, Head trail, Tommy bar, Long scoop for Hip for cemented stem, Tommy bar for rasp handle for cemented stem, Trial locating pin for cemented stem, Positioning bar for cemented stem, Head, dismantler for cemented stem, Introducer for cement restrictor, Head trial adaptor, Set of gauges, Ruller for uncemented stem, Rasp handle for uncemented stem, Trial neck for uncemented stem, Rasp for uncemented stem, Repositioning Lever for uncemented stem, Double Curved Gauge for uncemented stem, Proximal Trial Stem for uncemented stem, Gauge for medullary Cavity for uncemented stem, Reduction Lever for uncemented stem, Positioning bar for uncemented stem, Hammer for uncemented stem, Hex wrench for uncemented stem, Distal trial stem for uncemented stem, Proximal trial neck for uncemented stem, Ruller for uncemented stem, Hip head dismantler for uncemented, Trial adaptor for cemented stem. Class of medical device:Class A Material of construction:SS Dimension(if any): Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>
34	<p>Generic Name:Thick /Thin Guide Pin Model No.:NIL Intended Use:The guide pin is to be used facilitate precise placement of a cannulated screw during orthopedic surgery. Class of medical device:Class A Material of construction:SS Dimension(if any): Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>
35	<p>Generic Name:Vice Grip Model No.:NIL Intended Use:The product used to hold pliers. Class of medical device:Class A Material of construction:SS Dimension(if any): Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>
36	<p>Generic Name:Retractor Holder Model No.:NIL Intended Use:A mechanism to which surgical retractors are mounted to, in order for the retractors to hold back tissues. Class of medical device:Class A Material of construction:SS Dimension(if any): Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>

37	<p>Generic Name:Extractor Model No.:NIL Intended Use:An instrument, commonly known as a splinter probe, used to aid in the removal of foreign objects from superficial skin tissue. The device is single-use. These include Extractor rod, Extractor hammer, Extractor rod handle, Head extractor for cemented stem, Head extractor. Class of medical device:Class A Material of construction:SS Dimension(if any): Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>
38	<p>Generic Name:Bone Curette Model No.:NIL Intended Use:A handheld manual surgical instrument used for cutting and excising bone tissue typically during orthopedic surgery. It is typically a long, slender instrument with a handle at the proximal end and a concave, spoon-like tip which has a sharp edge, at the distal end. The bowl may be open (ring curette) or it may be double-ended and is used to facilitate the removal of the bone tissue without causing trauma to the surrounding muscles. This is a reusable device. Class of medical device:Class A Material of construction:SS Dimension(if any): Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>
39	<p>Generic Name:Surgical Mallet Model No.:NIL Intended Use:A handheld surgical instrument that is used by a surgeon to manually impart a force on another device during surgical intervention. Class of medical device:Class A Material of construction:SS Dimension(if any): Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>
40	<p>Generic Name:Dilator & accessories Model No.:NIL Intended Use:A surgical instrument used for enlarging cavities or openings during surgical procedures. This include dilator incision. Class of medical device:Class A Material of construction:SS Dimension(if any):7mm/8mm/9mm/10mm Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>
41	<p>Generic Name:Pliers Model No.:NIL Intended Use:The purpose of these instruments is to hold, bend or cut commonly used orthodontic materials such as wires. These include Wire bending pliers, Cerclip plier & locking plier. Class of medical device:Class A Material of construction:SS Dimension(if any):10mm/15mm/20mm/25mm Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>

42	<p>Generic Name:Pneumatic Tourniquet & its attachment Model No.:NIL Intended Use:The tourniquet used for stopping flow of blood through artery by compression. The attachment includes Consol unit & cuffs. Class of medical device:Class A Material of construction:SS Dimension(if any): Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>
43	<p>Generic Name:Knee System Instruments Model No.:NIL Intended Use:These are surgically invasive instruments which are used manually to assist during total knee arthroplasty. The devices are single use/reusable. The product does not include orthopedic implants. Class of medical device:Class B Material of construction:SS Dimension(if any):6mm/7mm Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>
44	<p>Generic Name:Hip System Instruments Model No.:NIL Intended Use:These are surgically invasive instruments which are used manually to assist in the implantation of the femoral or acetabular components in total or hemiarthroplasty. The devices are single use/reusable. The product does not include orthopedic implants. Class of medical device:Class B Material of construction:SS Dimension(if any):2.4mm/4.5mm/5mm/7mm Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>
45	<p>Generic Name:Arthroscopic Instruments Model No.:NIL Intended Use:These are surgically invasive instruments for manipulating and removing bone and bone fragments. Intended to use in orthoscopic surgical procedure. Class of medical device:Class B Material of construction:SS Dimension(if any): Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>
46	<p>Generic Name:Bone Chisel Model No.:NIL Intended Use:A single bladed surgical instrument, beveled on one side, that is intended for use in cutting or contouring bone. Widely used in orthopedic surgery. Class of medical device:Class A Material of construction:SS Dimension(if any): Shelflife:Non-Sterile (Nil) for Sterile till seal is intact. Sterile or Non sterile:Both Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>

Place: **GANDHINAGAR**

Date 28-Jun-23

State Licensing Authority

