



सत्यमेव जयते

FORM MD-10

[See sub-rule (1) rule 25]

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

Loan Licence Number: MFG/MD/2023/000536

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 M/s Universal Medicap Ltd, Post- Rania, Taluka- Savli,, Vadodara, Gujarat (India) - 391780 Telephone No.: 7567881887 FAX: 7567881887

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:Bone Screw Model No.:NIL Intended Use:The bone screw is intended to use for internal fixation of bone fractures and reconstruction of bones, there are several types of screw like locking head screw, general cortical screw or femur head bone screw are used for fixing of Femur head compression plate, locking plates which is used for osteotomy patients Examples of these internal fixations and reconstructions include compression fractures, intra-articular and extra-articular fractures, displaced fractures, osteotomies, non-unions and mal-unions. Class of medical device:Class C Material of construction:Titanium , SS 316L and SS 316LVM Dimension(if any): Shelflife:5 Year Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>

2	<p>Generic Name:Bone Plate</p> <p>Model No.:NIL</p> <p>Intended Use:The bone plate is intended to use for internal fixation of fractures and reconstruction of bones including the scapula, olecranon, humerus, radius, ulna, pelvis, tibia, fibula, femoral. Examples of these internal fixations and reconstructions include compression fractures, intra-articular and extra- articular fractures, displaced fractures, osteotomies, nonunions and mal-unions</p> <p>Class of medical device:Class C</p> <p>Material of construction:Titanium , SS 316L and SS 316LVM</p> <p>Dimension(if any):As per Licence Number: MFG/MD/2020/000186</p> <p>Shelflife:5 Year</p> <p>Sterile or Non sterile:Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>
3	<p>Generic Name:Wires and Pins</p> <p>Model No.:NIL</p> <p>Intended Use:These implants are used in human body to unite bones of different parts of the body. Wires are of different types which used in fractures of bones serving as ligament or muscle attachment. Wires are mainly indicated for both temporary and definitive fixation. These implants are used in human body to unite bones of different parts of the body. Pins are of different types which generally used with external fixator implants in Tibia, Femur & forearm bones.</p> <p>Class of medical device:Class C</p> <p>Material of construction:Titanium , SS 316L and SS 316LVM</p> <p>Dimension(if any):</p> <p>Shelflife:5 Year</p> <p>Sterile or Non sterile:Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>
4	<p>Generic Name:Spine Implants</p> <p>Model No.:NIL</p> <p>Intended Use:The Spinal Implant System is intended to promote fusion of the cervical and thoracic spine (C1-T3) for the following conditions: degenerative disc disease (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies); spondylolisthesis; spinal stenosis; trauma(fracture/dislocation); failed previous fusion; and/or tumors. The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1 -T3) spine. The uses of multi axial screws (poly axial)/ connectors are limited to placement in T1 -T3 vertebrae for treating thoracic conditions only. Screws are not intended to be placed in the cervical spine. Titanium rods are provided in various lengths and are used to connect pedicle screws (Mono & poly axial) and create a rigid structure.</p> <p>Class of medical device:Class C</p> <p>Material of construction:Titanium</p> <p>Dimension(if any):</p> <p>Shelflife:5 Year</p> <p>Sterile or Non sterile:Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>

5	<p>Generic Name:Interlocking Nail</p> <p>Model No.:NIL</p> <p>Intended Use::Intramedullary Nails implants are intended to be used for temporary fixation and stabilization of long bones in various anatomical regions such as proximal femurs, femoral shaft, tibia and humerus</p> <p>Class of medical device:Class C</p> <p>Material of construction:Titanium , SS 316L and SS 316LVM</p> <p>Dimension(if any):As per Licence Number: MFG/MD/2020/000186</p> <p>Shelflife:5 Year</p> <p>Sterile or Non sterile:Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):SORATH, SORATH ORTHO</p>
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Place:

Date29-May-23

Central Licensing Authority

