



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/2019/000007

1. M/s S.H.Pitkar Orthotools Pvt. Ltd., EL-32, J Block, MIDC Bhosari, Pune, Maharashtra (India) - 411026 Telephone No.: 02040706464 FAX: 020-46768107 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s S.H.Pitkar Orthotools Pvt. Ltd., EL-32, J Block, MIDC Bhosari, Pune, Maharashtra (India) - 411026 Telephone No.: 02040706464 FAX: 020-46768107

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:Intramedullary Locking Nails Model No.:Ultralock Nails - Diameter 8.0mm to 13mm ,SOL T nails - Diameter 8.0mm to 11mm , Universal locking tibia nails - Diameter 8.0mm to 11mm ,Universal locking femur nails - Diameter 9.0 mm to 12mm ,Trocantric femurol nails- 130° & 135° - Diameter 9.0mm to 12mm ,Interlocking nails-femur - Diameter 9.0mm to 13mm ,Interlocking nails-tibia - Diameter 9.0mm to 12mm ,Elastic nails - Diameter 2.0mm to 4.0mm ,Humerus nail - Diameter 6.0mm to 8.0mm ,Other misc nails - Diameter 2.0mm to 12mm</p> <p>Intended Use:The use of metallic surgical implants provides the orthopaedic surgeon a means of accurate bone fixation & helps generally in the management of fractures and reconstructive surgery. These implants are intended as aids to normal healing but are not intended to replace normal body structures or bear weight of the body in the presence of incomplete bone healing.</p> <p>Class of medical device:Class C Material of construction:SS 316 L & Titanium Dimension(if any):Various diameters & lengths Shelflife:N.A. Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):PITKAR</p>

2	<p>Generic Name:Pins</p> <p>Model No.:Threaded pins - Diameter 4.0mm ,Schanz screws - Diameter 2.5mm to 5.0mm ,Tapered threaded pins - Diameter 4.5mm to 6.0mm ,Steinman Pins - Diameter 2.0mm to 6.0mm</p> <p>Intended Use:i.Anatomical reduction of bony injuries. ii.High stability of the bone fracture segments. iii.Preservation of injured limb function. iv.Early mobilization of the patient.</p> <p>Class of medical device:Class C</p> <p>Material of construction:SS 316 L & Titanium</p> <p>Dimension(if any):Various diameters & lengths</p> <p>Shelflife:5 Years</p> <p>Sterile or Non sterile:Both</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):PITKAR</p>
3	<p>Generic Name:Endobutton</p> <p>Model No.:Endo button - Diameter 1.8 mm</p> <p>Intended Use:The ENDOBUTTON Fixation Devices are used for fixation of tendons and ligaments during orthopedic reconstruction procedures such as Anterior Cruciate Ligament reconstruction and acromioclavicular joint separations due to coracoclavicular ligament disruptions.</p> <p>Class of medical device:Class C</p> <p>Material of construction:Titanium</p> <p>Dimension(if any):Various diameters & lengths</p> <p>Shelflife:5 Years</p> <p>Sterile or Non sterile:Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):PITKAR</p>
4	<p>Generic Name:Hip Prosthesis</p> <p>Model No.:A. M. Prosthesis - Ball diameter 37 mm to 53 mm ,Thompson Prosthesis - Ball diameter 37 mm to 53 mm ,Bipolar Prosthesis - Ball diameter 37 mm to 56 mm</p> <p>Intended Use:Intended to be implanted to replace the articulating surface of the hip while preserving the femoral head and neck</p> <p>Class of medical device:Class C</p> <p>Material of construction:SS 316 L</p> <p>Dimension(if any):Various diameters & lengths</p> <p>Shelflife:5 Years</p> <p>Sterile or Non sterile:Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):PITKAR</p>

5	<p>Generic Name:Bone Plates</p> <p>Model No.:Low Contact Self compression hole plate - Diameter 3.0mm to 5.0mm ,Tubular plates - Diameter 1.0mm to 1.2mm ,Reconstruction plates - Diameter 2.5mm to 3.5mm,Locking plates - Diameter 1.2mm to 6.0mm,Hip Fix Plates - Diameter 6.5mm ,Other misc plates - Diameter 1.2mm to 6.0mm,L Plate Left & Right - Diameter 2.0mm ,T Plate - Diameter 2.0mm ,Spoon Plate - Diameter 2.0mm ,Clover leaf plate - Diameter 2.0mm ,T Buttress plate - Diameter 2.0mm ,L Buttress plate- Left & Right - Diameter 2.0mm ,Cobra head plate - Diameter 6.0mm ,Self compression Hole Plate - Diameter 3.0mm to 5.0mm ,L oblique long leg medium-right/left - Diameter 0.8mm,L oblique long leg large-right/left - Diameter 0.8mm,Orbital plate short bar - Diameter 0.6mm,Orbital plate with bar 0.6mm - Diameter 0.6mm,Condylar buttress plates with self compression holes - Diameter 5.0 mm ,Lateral tibia head buttress plate- Left & Right - Diameter 4.0mm ,Y plate - Diameter 1.2mm ,T plate right angled - Diameter 1.2mm ,T plate oblique angled - Diameter 1.2mm ,Dynamic condylar screw plate with self compression holes - Diameter 6.5mm ,Dynamic condylar screw plate with compression holes - Diameter 6.5mm ,X plate - Diameter 0.6mm to 2.0mm,L plate right angel short-right/left - Diameter 0.6mm to 1.0mm,L plate right angel long-right/left - Diameter 0.6mm to 1.0 mm,L plate oblique angle short-right/left - Diameter 0.6mm to 1.0mm,L plate oblique angle long-right/left - Diameter 0.6mm to 1.0mm,L oblique short leg small-right/left - Diameter 0.8mm,L oblique short leg medium-right/left - Diameter 0.8mm,Orbital plate - Diameter 0.6mm,T plate - Diameter 0.6mm to 1.0mm,Y plate narrow/broad - Diameter 0.6mm ,Double Y plate narrow - Diameter 0.6mm ,Double Y plate broad - Diameter 0.6mm to 1.0mm,Y plate short/long - Diameter 1.0mm,Mini plate with bar DCP short/long - Diameter 1.0mm,Mesh - Diameter 0.4 mm to 0.6mm,DCP Plate - Diameter 0.8mm,Chin plate - Diameter 0.8mm,Reconstruction plate with angle- left/right - Diameter 2.0mm,Reconstruction plate - Diameter 2.0mm,Frame plate rectangular - Diameter 1.0 mm,Frame plate radial - Diameter 1.0mm,Burr hole plate - Diameter 0.4mm,Mini plate - Diameter 0.6 mm to 1.2mm,Mini plate with long bar - Diameter 1.0mm,Mini plate with bar - Diameter 0.6mm to 1.2 mm</p> <p>Intended Use:The use of metallic surgical implants provides the orthopaedic surgeon a means of accurate bone fixation & helps generally in the management of fractures and reconstructive surgery. These implants are intended as aids to normal healing but are not intended to replace normal body structures or bear weight of the body in the presence of incomplete bone healing.</p> <p>Class of medical device:Class C</p> <p>Material of construction:SS 316 L & Titanium</p> <p>Dimension(if any):Various diameters & lengths</p> <p>Shelflife:N.A.</p> <p>Sterile or Non sterile:Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):PITKAR</p>
6	<p>Generic Name:Cages</p> <p>Model No.:PLIF Cages - Diameter 8mm to 12mm ,TLIF cages - Diameter 7mm to 10mm</p> <p>Intended Use:It is indicated for use with autogenous bone graft in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous spinal levels</p> <p>Class of medical device:Class C</p> <p>Material of construction:Titanium & PEEK</p> <p>Dimension(if any):Various diameters & lengths</p> <p>Shelflife:5 Years</p> <p>Sterile or Non sterile:Both</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):PITKAR</p>

7	<p>Generic Name: Intervertebral body fusion device</p> <p>Model No.: 37± 4mm - , 45± 4mm - Diameter 2.0mm , Poly Pedical screw-for lateral mass - Diameter 3.5mm , 4.3mm - , Occipital rod - Diameter 3.3mm , Locking head screw for occipital plate - Diameter 3.5mm , D connector for lateral mass - Diameter 8.0mm , D connector rod for lateral mass - Diameter 2.5mm , Cervical screws - Diameter 4.0mm to 4.35mm , Cervical plates - Diameter 2.0mm , Spinal Mesh - Diameter 10mm to 16mm , Bias screw - Diameter 3.5mm , Locking head screw-OCT - Diameter 3.5mm , Occipital T plates 31± 2mm - , 37± 4mm - , 45± 4mm - Diameter 2.0mm , Occipital Y plates 31± 2mm -</p> <p>Intended Use: The device is inserted into the intervertebral body space of the cervical or lumbosacral spine and is intended for intervertebral body fusion</p> <p>Class of medical device: Class D</p> <p>Material of construction: Titanium</p> <p>Dimension(if any): Various diameters & lengths</p> <p>Shelflife: N.A.</p> <p>Sterile or Non sterile: Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999): PITKAR</p>
8	<p>Generic Name: Pedicle screw spinal system</p> <p>Model No.: Poly Pedical screw-for small anatomy - Diameter 3.5mm, 4.3mm - , 5.0mm - , Spinal pre-cut rod for small anatomy - Diameter 4.3mm , Spinal rod - Diameter 5.0mm , D connector - Diameter 12mm , Pedical screws - Diameter 4.5mm, 5.5mm - , 6.5mm - , Bridge plates 30/34 - , 34/42 - , 40/53 - , 50/70 - ----- , Pedical screw-for small anatomy - Diameter 4.3mm, 5.0mm - , Spinal hook for lateral mass - Diameter 10mm , Spinal Hooks - Diameter 12.25mm to 15mm</p> <p>Intended Use: It is used to intended to provide immobilization and stabilization of spinal segments</p> <p>Class of medical device: Class C</p> <p>Material of construction: Titanium</p> <p>Dimension(if any): Various diameters & lengths</p> <p>Shelflife: N.A.</p> <p>Sterile or Non sterile: Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999): PITKAR</p>
9	<p>Generic Name: Cervical artificial disc</p> <p>Model No.: Cervical disc spacer - Diameter 4.0mm to 9.0mm</p> <p>Intended Use: Cervical artificial disc is indicated for reconstruction of the disc</p> <p>Class of medical device: Class D</p> <p>Material of construction: Titanium</p> <p>Dimension(if any): Various diameters & lengths</p> <p>Shelflife: N.A.</p> <p>Sterile or Non sterile: Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999): PITKAR</p>

10	<p>Generic Name:Bone screws</p> <p>Model No.:Cortical Screws - Diameter 2.7mm to 4.5mm,Cancellous Screws - Diameter 4.0mm to 6.5 mm,Malleolar Screws - Diameter 4.5mm,Cannulated Cancellous Screw - Diameter 4.0mm to 7.0mm, Hip fix Screw - Diameter 12.5mm,Screw for locking plates - Diameter 3.5mm to 5.0mm,Self tapping screws for locking nails - Diameter 3.8mm to 5.0mm,Cervical Screws - Diameter 6.5mm,Hip Pin - Diameter 6.0mm,Hip Bolt - Diameter 9.0mm,Interference Screw - Diameter 7.0mm to 9.0mm ,Other misc. screws - Diameter 3.8mm to 6.4mm,Interlocking screw - Diameter 3.8mm to 5.0mm, Antirotational screw - Diameter 6.4mm,Lag screw - Diameter 8.0mm,Self drilling screw - Diameter 1.5mm to 2.0mm ,Non self drilling screw - Diameter 1.5mm, 2.0mm, 2.4mm</p> <p>Intended Use:The use of metallic surgical implants provides the orthopaedic surgeon a means of accurate bone fixation & helps generally in the management of fractures and reconstructive surgery. These implants are intended as aids to normal healing but are not intended to replace normal body structures or bear weight of the body in the presence of incomplete bone healing.</p> <p>Class of medical device:Class C</p> <p>Material of construction:SS 316 L & Titanium</p> <p>Dimension(if any):Various diameters & lengths</p> <p>Shelflife:N.A.</p> <p>Sterile or Non sterile:Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):PITKAR</p>
----	--

Place:

Date 23-Jan-19

Central Licensing Authority

