

FORM MD-8

[See sub-rule (1) of rule 21 and sub-rule (2) of rule 21]

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

1. Name of Applicant: NISHTHA MEDIQUIP
2. Nature and constitution of manufacturer: Proprietary
3. (i) Corporate/ registered office address: M/s NISHTHA MEDIQUIP,
Nr. APMC MarkeT, 4th Floor, 423 City Gate, B/H Vishala
Hotel, Shahvadi
Ahmedabad, Ahmedabad, Gujarat (India) - 382405
Telephone No.: 9726960326 FAX: 8200759559 Email:
veer326wellortho@gmail.com
- (ii) Manufacturing site address/ Sterilization
site address: M/s PRAGATI SURGITECH,
49-50, Annapurna Industrial Estate, Inside Zaveri Estate,
Behind C.L.High School, Singarva- Kathwada Road,
Kathwada
, Ahmedabad, Gujarat (India) - 382430
Telephone No.: 9825048867 FAX: 9825048867
- (iii) Address for correspondence: M/s NISHTHA MEDIQUIP,
Nr. APMC MarkeT, 4th Floor, 423 City Gate, B/H Vishala
Hotel, Shahvadi
Ahmedabad, Ahmedabad, Gujarat (India) - 382405
Telephone No.: 9726960326 FAX: 8200759559 Email:
veer326wellortho@gmail.com
4. Details of medical device(s) to be manufactured

S.No.	Details Of Device(s)
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1. Generic Name :Bone Plate (Stainless Steel)
2. Brand Name(if registered under the Trade Marks Act, 1999) :NISHTHA MEDIQUIP
3. Notified Category :Orthopaedic Implants
4. Class of Medical Device :Class C
5. Shelflife :NIL
6. Sterilization:Non-Sterilized
7. Contains Drugs:No
8. Medical Device Grouping Category : Family
9. Grouping Description: NIL
10. Intended Use :These implants are used in human body to unite bones of different parts of the body. Bone plates are generally for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device.
11. Product Description: Bone Plates consists of various shapes and various sizes.
12. Material of Construction: STAINLESS STEEL 316L
13. Dimension: Various Dimensions
14. Storage Condition: Not Applicable
14. Pack Size: Single Unit per Pack
15. Accessory: NIL
16. Model No. :Locking Plates - - LCP Clavicle Hook Plate 3.5mm, LCP Superior Anterior Clavicle 3.5mm, LCP Superior Anterior Clavicle 3.5mm With Lateral Extension, LCP Proximal Humerus 3.5 mm,LCP Proximal Humerus Long Philos 3.5mm - LCP Proximal Humerus Philos 3.5mm, LCP Periarticular Proximal Humerus Plate 3.5mm, LCP Medial Distal Humerus 3.5 mm, 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 2.4mm 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 3.5 mm 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 4.5 mm, 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, L- Buttress Plate 4.5mm, One Third Tubular Plate 3.5mm, Semi Tubular Plates, Reconstruction Plate 3.5 mm, Reconstruction Y Plate 3.5mm, 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 3.5 mm Oblique Angle, T-Plate 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, Micro Reconstruction Plate(2.0mm), Micro LCP Condylar Plate (2.0mm), Micro LCP Y Plate (2.0 mm), LCP T Plate (Head Hole 2) (2.0mm), Rotation Correction Plate (2.0mm), Micro LCP Reconstruction Plate (2.0mm), Micro LCP Straight Plate (2.0mm), LCP Micro T Plate (Head Hole 3) (2.0mm), LCP Cloverleaf Fusion Plate-Standard (2.7mm), LCP Cloverleaf Fusion Plate-Short (2.7mm), LCP First MTP Fusion Plate-Small (Right-Left)(2.7mm), LCP First MTP Fusion Plate-Medium (Right-Left)(2.7mm),LCP First TMT Fusion Plate-Standard (2.7mm) - LCP First TMT Fusion Plate-Long (2.7mm), LCP L-Fusion Plate-Standard (Right-Left)(2.7mm), LCP L Fusion Plate-Short (Right-Left)(2.7mm), LCP Second TMT Fusion Plate-Standard (2.7 mm), LCP Fusion Plate-Straight (2.7mm), LCP T Fusion Plate-Standard (2.7mm), LCP T

	Fusion Plate-Short (2.7mm), LCP X Plate (2.7mm), LCP Calcaneal Plate (2.7mm) 17. Equivalence to predicate device : Yes
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1. Generic Name :Bone Plate (Titanium) 2. Brand Name(if registered under the Trade Marks Act, 1999) :NISHTHA MEDIQUIP 3. Notified Category :Orthopaedic Implants 4. Class of Medical Device :Class C 5. Shelflife :NIL 6. Sterilization:Non-Sterilized 7. Contains Drugs:No 8. Medical Device Grouping Category : Family 9. Grouping Description: NIL 10. Intended Use :These implants are used in human body to unite bones of different parts of the body. Bone plates are generally for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device. 11. Product Description: Bone Plates consists of various shapes and various sizes. 12. Material of Construction: TITANIUM 13. Dimension: Various Dimensions 14. Storage Condition: Not Applicable 14. Pack Size: Single Unit per Pack 15. Accessory: NIL 16. Model No. :Locking Plates - - LCP Clavicle Hook Plate 3.5mm, LCP Superior Anterior Clavicle 3.5mm, LCP Superior Anterior Clavicle 3.5mm With Lateral Extension, LCP Proximal Humerus 3.5 mm,LCP Proximal Humerus Long Philos 3.5mm - LCP Proximal Humerus Philos 3.5mm, LCP Periarticular Proximal Humerus Plate 3.5mm, LCP Medial Distal Humerus 3.5 mm, 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 2.4mm Head 03 Hole, LCP Distal Radius L Plate 3.5 mm 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 3.5 mm 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 4.5 mm, 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, L- Buttress Plate 4.5mm, One Third Tubular Plate 3.5mm, Semi Tubular Plates, Reconstruction Plate 3.5 mm, Reconstruction Y Plate 3.5mm, 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 3.5 mm Oblique Angle, T-Plate 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, Micro Reconstruction Plate(2.0mm), Micro LCP Condylar Plate (2.0mm), Micro LCP Y Plate (2.0 mm), LCP T Plate (Head Hole 2) (2.0mm), Rotation Correction Plate (2.0mm), Micro LCP Reconstruction Plate (2.0mm), Micro LCP Straight Plate (2.0mm), LCP Micro T Plate (Head Hole 3) (2.0mm), LCP Cloverleaf Fusion Plate-Standard (2.7mm), LCP Cloverleaf Fusion Plate-Short (2.7mm),LCP First MTP Fusion Plate-Small (Right-Left)(2.7mm) - LCP First MTP Fusion Plate-Medium (Right-Left)(2.7mm), LCP First TMT Fusion Plate-Standard (2.7mm), LCP First TMT Fusion Plate-Long (2.7mm), LCP L-Fusion Plate-Standard (Right-Left)(2.7mm), LCP L Fusion Plate-Short (Right-Left)(2.7mm), LCP Second TMT Fusion Plate-Standard (2.7 mm), LCP Fusion Plate-Straight (2.7mm), LCP T Fusion Plate-Standard (2.7mm), LCP T
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	Fusion Plate-Short (2.7mm), LCP X Plate (2.7mm), LCP Calcaneal Plate (2.7mm). 17. Equivalence to predicate device :Yes
3	1. Generic Name :Bone Screw (Stainless Steel) 2. Brand Name(if registered under the Trade Marks Act, 1999) :NISHTHA MEDIQUIP 3. Notified Category :Orthopaedic Implants 4. Class of Medical Device :Class C 5. Shelflife :NIL 6. Sterilization:Non-Sterilized 7. Contains Drugs:No 8. Medical Device Grouping Category : Family 9. Grouping Description: NIL 10. Intended Use :Bone Screws are intended to treat fractures and osteotomies of various bones, including the clavicle, acetabulum., pelvis, scapula, humerus, radius, ulna, femur, tibia, phalanges, carpals, metacarpals, tarsals, metatarsals and fibula. 11. Product Description: Bone Screws consists of various shapes and various sizes. 12. Material of Construction: STAINLESS STEEL 316L 13. Dimension: Various Dimensions 14. Storage Condition: Not Applicable 14. Pack Size: Single Unit per Pack 15. Accessory: NIL 16. Model No. :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 3.5 mm, 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 4.0 mm & 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 3.5 mm & 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, Herbert screw, Apfn Screw, Apfn Blade, Mini Screw (Single Slotted) (1.5mm, 2.0mm,2.5mm), Mini Screw (Cross Slotted) (Self Drilling) (1.5mm,2.0mm,2.5mm), Mini Screw (Cross Slotted) (Self Tapping) (1.5mm,2.0mm,2.5mm), Mini Screw (Cross Slotted) (Without Self Tapping) (1.5mm,2.0mm,2.5mm), Emergency Screw (Single Slotted) (1.8mm, 2.3mm,2.7mm),Intermaxillary Fixation Screw(I.M.F.) - With Hole/With Groove (2.0mm, 2.5 mm), Mini Leg Screw (Single Slotted) (2.0mm, 2.5mm), Mini Screw (2.7mm) (5mm Single Slot Head) Mini Screw Cross slotted Self Drilling cum Self tapping (1.6mm), Locking Head Screw (2.0mm), Cortex Screw (2.0mm), Cortex Screw Star Drive (2.7 mm), Locking Head Screw With Star Drive (2.7mm). 17. Equivalence to predicate device :Yes

- 1. Generic Name :** Bone Screws (Titanium)
- 2. Brand Name(if registered under the Trade Marks Act, 1999) :** NISHTHA MEDIQUIP
- 3. Notified Category :** Orthopaedic Implants
- 4. Class of Medical Device :** Class C
- 5. Shelflife :** NIL
- 6. Sterilization:** Non-Sterilized
- 7. Contains Drugs:** No
- 8. Medical Device Grouping Category :** Family
- 9. Grouping Description:** NIL
- 10. Intended Use :** Bone Screws are intended to treat fractures and osteotomies of various bones, including the clavicle, acetabulum., pelvis, scapula, humerus, radius, ulna, femur, tibia, phalanges, carpals, metacarpals, tarsals, metatarsals and fibula.
- 11. Product Description:** Bone Screws consists of various shapes and various sizes.
- 12. Material of Construction:** TITANIUM
- 13. Dimension:** Various Dimensions
- 14. Storage Condition:** Not Applicable
- 14. Pack Size:** Single Unit per Pack
- 15. Accessory:** NIL
- 16. Model No. :** 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 3.5 mm, 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 4.0 mm & 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 3.5 mm & 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, Herbert screw, Apfn Screw, Apfn Blade, Mini Screw (Single Slotted) (1.5mm, 2.0mm, 2.5mm), Mini Screw (Cross Slotted) (Self Drilling) (1.5mm, 2.0mm, 2.5mm), Mini Screw (Cross Slotted) (Self Tapping) (1.5mm, 2.0mm, 2.5mm), Mini Screw (Cross Slotted) (Without Self Tapping) (1.5mm, 2.0mm, 2.5mm), Emergency Screw (Single Slotted) (1.8mm, 2.3mm, 2.7mm), Intermaxillary Fixation Screw(I.M.F.) With Hole/With Groove (2.0mm, 2.5 mm), Mini Leg Screw (Single Slotted) - (2.0mm, 2.5mm), Mini Screw (2.7mm) (5mm Single Slot Head) Mini Screw Cross slotted Self Drilling cum Self tapping (1.6mm), Locking Head Screw (2.0mm), Cortex Screw (2.0mm), Cortex Screw Star Drive (2.7 mm), Locking Head Screw With Star Drive (2.7mm).
- 17. Equivalence to predicate device :** Yes

- 1. Generic Name :**Arthroscopy Implants (Stainless Steel)
- 2. Brand Name(if registered under the Trade Marks Act, 1999) :**NISHTHA MEDIQUIP
- 3. Notified Category :**Orthopaedic Implants
- 4. Class of Medical Device :**Class C
- 5. Shelflife :**NIL
- 6. Sterilization:**Non-Sterilized
- 7. Contains Drugs:**No
- 8. Medical Device Grouping Category :** Family
- 9. Grouping Description:** NIL
- 10. Intended Use :**The Arthroscopy Implants are intended to used especially for attaching the damaged / strained soft tissues and bone fragments in repair treatment of cruciate ligament (anterior or posterior) of the knee joint and the rotator cuff of the shoulder joints. They are intended to be used for arthroscopic and less invasive approach.
- 11. Product Description:** The Arthroscopy Implants are single use device supplied Non-sterile. The devices are available in different sizes.
- 12. Material of Construction:** STAINLESS STEEL 316L
- 13. Dimension:** Various Dimensions
- 14. Storage Condition:** Not Applicable
- 14. Pack Size:** Single Unit per Pack
- 15. Accessory:** NIL
- 16. Model No. :**ACL Screws or Interference Screw Full Threaded - - Dia. (Ø) 5.0 mm to 12.0 mm - Length 15 mm to 40 mm, Endo-Button - Length 12 mm to 40 mm, Endo-Button with Loop CL (Continues Loop) - Length 12 mm to 40 mm,Endo-Button with Adjustable Loop 4T - - Length 12 mm to 80 mm, No Button with Adjustable Loop - Length 12 mm to 80 mm, OC Loop Washer ABS Button - Length 15 mm to 40 mm, Suture Disc Round Hole, Tibial Suture Disc - Sizes: Dynamic / Round Hole, Hole Tibial Post Screw - Dia. (Ø) 5.0 mm to 13.0 mm - Length 25 mm to 50 mm, Suture Disc D'Hole Washer, Spiked Staple, Spiked Washer - Dia. (Ø) 3.0 mm to 8.0 mm - Length 15 mm to 40 mm, Anchor Suture - Dia. (Ø) 2.8 mm to 7.0 mm, Anchor Suture Preloaded - Dia. (Ø) 2.8 mm to 7.0 mm,Anchor Suture Preloaded With Needle - - Dia. (Ø) 2.0 mm to 8.0 mm, Arthroscopy Implant, Fiber Single Needle White - Length 300 mm 900 mm, Fiber Excel 4 In 1 White - Length 300 mm to 900 mm, Fiber Single Needle White & Blue - Length 300 mm to 900 mm, Bioabsorbable ACL Screws or Interference Screw Full Threaded - Dia. (Ø) 5.0 mm to 12.0 mm - Length 15 mm to 40 mm, Fiber Single Needle White & Black - Length 300 mm to 900 mm, Fiber Single Needle White - Length 300 mm to 900 mm, Wire Fiber Tape Sterile - Length 300 mm to 900 mm,Meniscus Needle With Fiber - - Length 300 mm to 900 mm, Meniscus Fiber - Length 300 mm to 900 mm, Anchor Suture Preloaded - Dia. (Ø) 2.8 mm to 6.5 mm - Length 15 mm to 40 mm, Lateral Row Anchor Suture Preloaded - Dia. (Ø) 5.0 mm to 10.0 mm - Length 25 mm to 50 mm, Suture Anchor - Length 2.5 mm to 7.0 mm, Suture Anchor Knotless - Length 2.5 mm to 5.0 mm, U type Needle with Fiber
- 17. Equivalence to predicte device :**Yes

- 1. Generic Name :**Arthroscopy Implants (Titanium)
- 2. Brand Name(if registered under the Trade Marks Act, 1999) :**NISHTHA MEDIQUIP
- 3. Notified Category :**Orthopaedic Implants
- 4. Class of Medical Device :**Class C
- 5. Shelflife :**NIL
- 6. Sterilization:**Non-Sterilized
- 7. Contains Drugs:**No
- 8. Medical Device Grouping Category :** Family
- 9. Grouping Description:** NIL
- 10. Intended Use :**The Arthroscopy Implants are intended to used especially for attaching the damaged / strained soft tissues and bone fragments in repair treatment of cruciate ligament (anterior or posterior) of the knee joint and the rotator cuff of the shoulder joints. They are intended to be used for arthroscopic and less invasive approach.
- 11. Product Description:** The Arthroscopy Implants are single use device supplied Non-sterile. The devices are available in different sizes.
- 12. Material of Construction:** TITANIUM
- 13. Dimension:** Various Dimensions
- 14. Storage Condition:** Not Applicable
- 14. Pack Size:** Single Unit per Pack
- 15. Accessory:** NIL
- 16. Model No. :**ACL Screws or Interference Screw Full Threaded - - Dia. (Ø) 5.0 mm to 12.0 mm - Length 15 mm to 40 mm, Endo-Button - Length 12 mm to 40 mm, Endo-Button with Loop CL (Continues Loop) - Length 12 mm to 40 mm,Endo-Button with Adjustable Loop 4T - - Length 12 mm to 80 mm, No Button with Adjustable Loop - Length 12 mm to 80 mm, OC Loop Washer ABS Button - Length 15 mm to 40 mm, Suture Disc Round Hole, Tibial Suture Disc - Sizes: Dynamic / Round Hole, Hole Tibial Post Screw - Dia. (Ø) 5.0 mm to 13.0 mm - Length 25 mm to 50 mm, Suture Disc D'Hole Washer, Spiked Staple, Spiked Washer - Dia. (Ø) 3.0 mm to 8.0 mm - Length 15 mm to 40 mm, Anchor Suture - Dia. (Ø) 2.8 mm to 7.0 mm, Anchor Suture Preloaded - Dia. (Ø) 2.8 mm to 7.0 mm,Anchor Suture Preloaded With Needle - - Dia. (Ø) 2.0 mm to 8.0 mm, Arthroscopy Implant, Fiber Single Needle White - Length 300 mm 900 mm, Fiber Excel 4 In 1 White - Length 300 mm to 900 mm, Fiber Single Needle White & Blue - Length 300 mm to 900 mm, Bioabsorbable ACL Screws or Interference Screw Full Threaded - Dia. (Ø) 5.0 mm to 12.0 mm - Length 15 mm to 40 mm, Fiber Single Needle White & Black - Length 300 mm to 900 mm, Fiber Single Needle White - Length 300 mm to 900 mm, Wire Fiber Tape Sterile - Length 300 mm to 900 mm, Meniscus Needle With Fiber - - Length 300 mm to 900 mm, Meniscus Fiber - Length 300 mm to 900 mm, Anchor Suture Preloaded - Dia. (Ø) 2.8 mm to 6.5 mm - Length 15 mm to 40 mm, Lateral Row Anchor Suture Preloaded - Dia. (Ø) 5.0 mm to 10.0 mm - Length 25 mm to 50 mm, Suture Anchor - Length 2.5 mm to 7.0 mm, Suture Anchor Knotless - Length 2.5 mm to 5.0 mm, U type Needle with Fiber
- 17. Equivalence to prediecte device :**Yes

1. Generic Name :Bone Nail (Stainless Steel) 2. Brand Name(if registered under the Trade Marks Act, 1999) :NISHTHA MEDIQUIP 3. Notified Category :Orthopaedic Implants 4. Class of Medical Device :Class C 5. Shelflife :NIL 6. Sterilization:Non-Sterilized 7. Contains Drugs:No 8. Medical Device Grouping Category : Family 9. Grouping Description: NIL 10. Intended Use :Interlocking Intramedullary Nails are intended to use for simple and complex long bone fractures which is severely comminuted, spiral, large oblique and segmental fractures; non-unions and mal-unions; polytrauma and multiple fractures; prophylactic nailing of impending pathologic fractures and grafting supra condylar fractures for bone lengthening and shortening. Interlocking Nails are indicated for fixation of fractures that occur in between the proximal and distal third of the long bones being treated. 11. Product Description: Intramedullary Nail is a closed section, cannulated, thick walled, mirror finished, curved' intramedullary fixation device containing two proximal and two distal holes to accept locking screws which thread transversely though the proximal and distal. 12. Material of Construction: STAINLESS STEEL 316L 13. Dimension: Various Dimensions 14. Storage Condition: Not Applicable 14. Pack Size: Single Unit per Pack 15. Accessory: NIL 16. Model No. :Universal Interlocking Tibial Nail Size - - 8.0mm to 14mm Length: 240mm to 500mm, Universal Interlocking Femoral Nail Size: 8.0mm to 14mm Length: 240mm to 500mm,Tibia Interlocking Nail Size - - 8.0mm to 14mm Length: 240mm to 500mm, Femoral Interlocking Nail Size: 8.0mm to 14mm Length: 240mm to 500mm, Reconstruction Femoral Nail Size: 8.0 mm to 16mm Length: 260mm to 540mm, Supera Condylar Nail Size:8.0mm to 16mm Length: 150mm to 500mm Humeral Interlocking Nail Size: 5.0mm to 10mm Length: 100mm to 500mm, Proximal Femoral Nail (130°/135°) Size: 8.0mm to 14mm Length: 150mm to 300 mm, Long Proximal Femoral Nail (130°/135°)(Right / Left) Size:8.0 mm to 14mm Length: 250mm to 540mm,Enders Nail Size - - 2.0mm,4.5 mm Length: 150mm to 500mm, K Nail Size: 5.0mm to 16mm Length: 200mm to 600mm, Rush Nail Size: 1.5mm to 8.0mm Length: 100mm to 500mm, Square Nail Radius Size: 1.5mm to 5.0mm Length: 100mm to 500mm, Square Nail Ulna Size: Size: 1.5mm to 5.0mm Length: 100mm to 500mm, Elastic Nail Size: 1.5mm to 5.0mm Length: 100mm to 500mm, Smart Tibia Nail Size 8mm to 14mm Length: 260mm to 500mm, Expert Tibia Interlocking Nail Size: 8.0mm to 14mm Length: 260mm to 500mm, Expert Femoral Interlocking Nail Size: 8.0mm to 14mm Length: 260mm to 540mm,Antigrade Femoral Nail (AFN) Size - - 8.0mm to 14mm Length: 240mm to 440mm, Multilock Femoral Nail Size: 8.0mm to 14mm Length: 240mm to 540mm, Trochanteric Femoral Nail (130°/135°) Size: 8.0mm to 14mm Length: 150mm to 200mm, Sirius femur nail size : 8mm to 14 mm Length : 240 mm to 540 mm, Multilock Humeral Nail Size: 6.0mm to 10mm Length: 100mm to 500mm, Unreamed Femoral Nail Size: 8.0mm to 14mm Length: 250mm to 600mm,Unreamed Tibia Nail Size - 8.0mm to 14mm Length: 250mm to 600mm, End Cap, PFNA2 Nail 125°/135°/130° Size: 9.0mm to 12mm Length: 170mm to 250mm, Long PFNA2 Nail (Left / Right) 125°/135°/130° Size: 8.0 mm to 14mm Length: 170mm to mm, Sirius Nail Size:8mm to 14mm Size: 240mm to 540mm 17. Equivalence to prediecte device :Yes

1. Generic Name :Bone Nail (Titanium) 2. Brand Name(if registered under the Trade Marks Act, 1999) :NISHTHA MEDIQUIP 3. Notified Category :Orthopaedic Implants 4. Class of Medical Device :Class C 5. Shelflife :NIL 6. Sterilization:Non-Sterilized 7. Contains Drugs:No 8. Medical Device Grouping Category : Family 9. Grouping Description: NIL 10. Intended Use :Interlocking Intramedullary Nails are intended to use for simple and complex long bone fractures which is severely comminuted, spiral, large oblique and segmental fractures; non-unions and mal-unions; polytrauma and multiple fractures; prophylactic nailing of impending pathologic fractures and grafting supra condylar fractures for bone lengthening and shortening. Interlocking Nails are indicated for fixation of fractures that occur in between the proximal and distal third of the long bones being treated. 11. Product Description: Intramedullary Nail is a closed section, cannulated, thick walled, mirror finished, curved' intramedullary fixation device containing two proximal and two distal holes to accept locking screws which thread transversely though the proximal and distal. 12. Material of Construction: TITANIUM 13. Dimension: Various Dimensions 14. Storage Condition: Not Applicable 14. Pack Size: Single Unit per Pack 15. Accessory: NIL 16. Model No. :Universal Interlocking Tibial Nail Size - - 8.0mm to 14mm Length: 240mm to 500mm, Universal Interlocking Femoral Nail Size: 8.0mm to 14mm Length: 240mm to 500mm,Tibia Interlocking Nail Size - - 8.0mm to 14mm Length: 240mm to 500mm, Femoral Interlocking Nail Size: 8.0mm to 14mm Length: 240mm to 500mm, Reconstruction Femoral Nail Size: 8.0 mm to 16mm Length: 260mm to 540mm, Supera Condylar Nail Size:8.0mm to 16mm Length: 150mm to 500mm Humeral Interlocking Nail Size: 5.0mm to 10mm Length: 100mm to 500mm, Proximal Femoral Nail (130°/135°) Size: 8.0mm to 14mm Length: 150mm to 300 mm, Long Proximal Femoral Nail (130°/135°)(Right / Left) Size:8.0 mm to 14mm Length: 250mm to 540mm,Enders Nail Size - - 2.0mm,4.5 mm Length: 150mm to 500mm, K Nail Size: 5.0mm to 16mm Length: 200mm to 600mm, Rush Nail Size: 1.5mm to 8.0mm Length: 100mm to 500mm, Square Nail Radius Size: 1.5mm to 5.0mm Length: 100mm to 500mm, Square Nail Ulna Size: Size: 1.5mm to 5.0mm Length: 100mm to 500mm, Elastic Nail Size: 1.5mm to 5.0mm Length: 100mm to 500mm, Smart Tibia Nail Size 8mm to 14mm Length: 260mm to 500mm, Expert Tibia Interlocking Nail Size: 8.0mm to 14mm Length: 260mm to 500mm, Expert Femoral Interlocking Nail Size: 8.0mm to 14mm Length: 260mm to 540mm,Antigrade Femoral Nail (AFN) Size - 8.0mm to 14mm Length: 240mm to 440mm,Multilock Femoral Nail Size - 8.0mm to 14mm Length: 240mm to 540mm, Trochanteric Femoral Nail (130°/135°) Size: 8.0mm to 14mm Length: 150mm to 200mm, Sirius femur nail size : 8mm to 14 mm Length : 240 mm to 540 mm, Multilock Humeral Nail Size: 6.0mm to 10mm Length: 100mm to 500mm, Unreamed Femoral Nail Size: 8.0mm to 14mm Length: 250mm to 600mm,Unreamed Tibia Nail Size - 8.0mm to 14mm Length: 250mm to 600mm, End Cap, PFNA2 Nail 125°/135°/130° Size: 9.0mm to 12mm Length: 170mm to 250mm, Long PFNA2 Nail (Left / Right) 125°/135°/130° Size: 8.0 mm to 14mm Length: 170mm to mm, Sirius Nail Size:8mm to 14mm Size: 240mm to 540mm. 17. Equivalence to prediecte device :Yes

- 1. Generic Name :** Bone Pins and Wires (Stainless Steel 316L)
- 2. Brand Name (if registered under the Trade Marks Act, 1999) :** NISHTHA MEDIQUIP
- 3. Notified Category :** Orthopaedic Implants
- 4. Class of Medical Device :** Class C
- 5. Shelflife :** NIL
- 6. Sterilization:** Non-Sterilized
- 7. Contains Drugs:** No
- 8. Medical Device Grouping Category :** Family
- 9. Grouping Description:** NIL
- 10. Intended Use :** Pins and Wires is intended for use in fixation of bone fractures, fusion of joints or bone reconstruction, for osteotomies in the presence of adequate immobilization and as guide pins for insertion of other implants.
- 11. Product Description:** Pins and Wires come in different sizes and are used to hold bone fragments together (pin fixation) or to provide an anchor for skeletal traction. To ensure the multi-use of these devices, many different models are available.
- 12. Material of Construction:** STAINLESS STEEL 316L
- 13. Dimension:** Various Dimensions
- 14. Storage Condition:** Not Applicable
- 14. Pack Size:** Single Unit per Pack
- 15. Accessory:** NIL
- 16. Model No. :** Front Threaded Schanz Pin - - Dia. (Ø) 1.5 mm to 6.0 mm Length: 50 mm to 500 mm, Front Threaded Schanz Pin HA Coated - Dia. (Ø) 1.5 mm to 6.0 mm Length: 50 mm to 500 mm, Front Threaded Tapered Schanz Pin - - Dia. (Ø) 1.5 mm to 6.0 mm Length: 50 mm to 500 mm, Front Threaded Tapered Schanz Pin Ha Coated - Dia. (Ø) 1.5 mm to 6.0 mm Length: 50 mm to 500 mm, Steinmann Pin - Dia. (Ø) 1.5 mm to 8.0 mm Length: 50 mm to 500 mm, K. Wire Single/Double Ended - Dia. (Ø) 0.8 mm to 6.0 mm Length: 50 mm to 500 mm, K. Wire Single/Double Ended Threaded - Dia. (Ø) 0.8 mm to 6.0 mm Length: 50 mm to 500 mm, S.S. Wire (Suture) Reel - Length: 16 SWG to 30 SWG, Illizarov Wire Baynot/Trocar Point - Dia. (Ø) 1.5 mm to 6.0 mm Length: 250 mm to 500 mm, Gigli saw wire - Guide wire Size : 0.8 mm to 4.0 mm Length : 100 mm to 500 mm , Guide wire (bolt tip) Size : 0.8 mm to 4.0 mm Length : 100 mm to 500 mm, Olive Wire Baynomt/Trocar Point - Dia. (Ø) 1.5 mm to 6.0 mm Length: 250 mm to 500 mm, Front Threaded Self Drilling And Self Tapping Tappered Schanz Pin - Dia. (Ø) 1.5 mm to 6.0 mm Length: 50 mm to 500 mm, Front Threaded Self Drilling And Self Tapping Tappered Schanz Pin HA Coated - - Dia. (Ø) 1.5 mm to 6.0 mm Length: 50 mm to 500 mm, Denham Pin or Centrally Threaded Pin - Dia. (Ø) 1.5 mm to 8.0 mm Length: 80 mm to 500 mm, U Type Staple (Epiphyseal) - Dia. (Ø) 1.0 mm to 6.0 mm Length: 5 mm to 100 mm, Pins - Dia. (Ø) 1.0 mm to 6.0 mm Length: 50 mm to 500 mm, Coventry Staple - Dia. (Ø) 1.5 mm to 6.0 mm Length: 05 mm to 100 mm
- 17. Equivalence to predicate device :** Yes

- 1. Generic Name :** Bone Pins and Wires (Titanium)
- 2. Brand Name (if registered under the Trade Marks Act, 1999) :** NISHTHA MEDIQUIP
- 3. Notified Category :** Orthopaedic Implants
- 4. Class of Medical Device :** Class C
- 5. Shelflife :** NIL
- 6. Sterilization:** Non-Sterilized
- 7. Contains Drugs:** No
- 8. Medical Device Grouping Category :** Family
- 9. Grouping Description:** NIL
- 10. Intended Use :** Pins and Wires is intended for use in fixation of bone fractures, fusion of joints or bone reconstruction, for osteotomies in the presence of adequate immobilization and as guide pins for insertion of other implants.
- 11. Product Description:** Pins and Wires come in different sizes and are used to hold bone fragments together (pin fixation) or to provide an anchor for skeletal traction. To ensure the multi-use of these devices, many different models are available.
- 12. Material of Construction:** TITANIUM
- 13. Dimension:** Various Dimensions
- 14. Storage Condition:** Not Applicable
- 14. Pack Size:** Single Unit per Pack
- 15. Accessory:** NIL
- 16. Model No. :** Front Threaded Schanz Pin - - Dia. (Ø) 1.5 mm to 6.0 mm Length: 50 mm to 500 mm, Front Threaded Schanz Pin HA Coated - Dia. (Ø) 1.5 mm to 6.0 mm Length: 50 mm to 500 mm, Front Threaded Tapered Schanz Pin - Pin - Dia. (Ø) 1.5 mm to 6.0 mm Length: 50 mm to 500 mm, Front Threaded Tapered Schanz Pin Ha Coated - Dia. (Ø) 1.5 mm to 6.0 mm Length: 50 mm to 500 mm, Steinmann Pin - Dia. (Ø) 1.5 mm to 8.0 mm Length: 50 mm to 500 mm, K. Wire Single/Double Ended - Dia. (Ø) 0.8 mm to 6.0 mm Length: 50 mm to 500 mm, K. Wire Single/Double Ended Threaded - Dia. (Ø) 0.8 mm to 6.0 mm Length: 50 mm to 500 mm, S.S. Wire (Suture) Reel - Length: 16 SWG to 30 SWG, Illizarov Wire Baynot/Trocar Point - - Dia. (Ø) 1.5 mm to 6.0 mm Length: 250 mm to 500 mm, Gigli saw wire , Guide wire Size : 0.8 mm to 4.0 mm Length : 100 mm to 500 mm , Guide wire (bolt tip) Size : 0.8 mm to 4.0 mm Length : 100 mm to 500 mm, Olive Wire Baynomt/Trocar Point - Dia. (Ø) 1.5mm to 6.0 mm Length: 250 mm to 500 mm, Front Threaded Self Drilling And Self Tapping Tappered Schanz Pin - Dia. (Ø) 1.5 mm to 6.0 mm Length: 50 mm to 500 mm, Front Threaded Self Drilling And Self Tapping Tappered Schanz Pin HA Coated - - Dia. (Ø) 1.5 mm to 6.0 mm Length: 50 mm to 500 mm, Denham Pin or Centrally Threaded Pin - Dia. (Ø) 1.5 mm to 8.0 mm Length: 80 mm to 500 mm, U Type Staple (Epiphyseal) - Dia. (Ø) 1.0 mm to 6.0 mm Length: 5 mm to 100 mm, Pins - Dia. (Ø) 1.0 mm to 6.0 mm Length: 50 mm to 500 mm, Coventry Staple - Dia. (Ø) 1.5 mm to 6.0 mm Length: 05 mm to 100 mm
- 17. Equivalence to predicate device :** Yes

- 1. Generic Name :**Spinal Implant (Stainless Steel)
- 2. Brand Name(if registered under the Trade Marks Act, 1999) :**NISHTHA MEDIQUIP
- 3. Notified Category :**Orthopaedic Implants
- 4. Class of Medical Device :**Class C
- 5. Shelflife :**NIL
- 6. Sterilization:**Non-Sterilized
- 7. Contains Drugs:**No
- 8. Medical Device Grouping Category :** Family
- 9. Grouping Description:** NIL
- 10. Intended Use :**Spinal implants are used to stabilize the unstable spine caused by trauma or by slipped vertebrae (spondylolisthesis) originating from degenerative intervertebral disks. Surgical stabilization can be achieved from either the anterior or posterior approach.
- 11. Product Description:** Spinal Implant consists of rods or plates, anterior screws, pedicle screws, sacral/iliac screws, hooks, connectors, crosslinks, fasteners. These spinal Implants are single use device supplied Non-sterile. The devices are available in different sizes.
- 12. Material of Construction:** STAINLESS STEEL 316L
- 13. Dimension:** Various Dimensions
- 14. Storage Condition:** Not Applicable
- 14. Pack Size:** Single Unit per Pack
- 15. Accessory:** NIL
- 16. Model No. :**Monoaxial Screw - - Dia. (Ø) 3.5 mm to 8.0 mm - Length 20 mm to 100mm, Polyaxial Screw - Dia. (Ø) 3.5 mm to 8.0 mm - Length 20 mm to 100mm,Reduction Monoaxial Screw - - Dia. (Ø) 3.5 mm to 8.0 mm - Length 20 mm to 100mm, Reduction Polyaxial Screw - Dia. (Ø) 3.5 mm to 8.0 mm - Length 20 mm to 100mm, Dual Thread Monoaxial Screw - Dia. (Ø) 3.5 mm to 8.0 mm - Length 20 mm to 100mm, Dual Thread Polyaxial Screw - Dia. (Ø) 3.5 mm to 8.0 mm - Length 20 mm to 100mm, Dual Thread Reduction Monoaxial Screw - Dia. (Ø) 3.5 mm to 8.0 mm - Length 20 mm to 100mm, Dual Thread Reduction Polyaxial Screw - Dia. (Ø) 3.5 mm to 8.0 mm - Length 20 mm to 100mm, Spinal Rod - Dia. (Ø) 3.0 mm to 7.0 mm - Length 20 mm to 600 mm,Spinal Connector Rod - - Dia. (Ø) 3.4 mm to 5.0 mm - Length 50 mm to 350mm, Domino Connector - Dia. (Ø) 5.0 mm to 7.0 mm - Length 20 mm to 40 mm, Spinal Transverse Connector - Dia. (Ø) 4.0 mm to 7.0 mm - Length 10 mm to 40 mm, Lateral / Elia Connector - Dia. (Ø) 4.0 mm to 7.0 mm - Length 10 mm to 50 mm, Pedical hook(diff. size) , Lamina hook (diff. size) , Lamina hook wide blade (diff. size) , Lamina hook narrow blade (diff. size) , occipital hook (diff. size) , occifix plate size : 50 mm to 250mm , occifix rod Size : 50 mm to 250 mm , triangle connector size : 3.0 mm to 6.0 mm,spinal Crosslink Connector - - Dia. (Ø) 4.0 mm to 7.0 mm - Length 20 mm to 200 mm, Fenestrated Monoaxial Screw (Cannulated) - Dia. (Ø) 3.5 mm to 8.0 mm - Length 20 mm to 100 mm, Fenestrated Polyaxial Screw (Cannulated) - Dia. (Ø) 3.5 mm to 8.0 mm - Length 20 mm to 100 mm, Fenestrated Reduction Monoaxial Screw (Cannulated)- Dia. (Ø) 3.5 mm to 8.0 mm - Length 20 mm to 100 mm, Fenestrated Reduction Polyaxial Screw (Cannulated) - Dia. (Ø) 3.5 mm to 8.0 mm -Length 20 mm to 100 mm, Fenestrated Dual Thread Monoaxial Screw (Cannulated) - Dia. (Ø) 3.5 mm to 8.0 mm - Length 20 mm to 100 mm,Fenestrated Dual Thread Polyaxial Screw (Cannulated) - - Dia. (Ø) 3.5 mm to 8.0 mm - Length 20 mm to 100 mm, Fenestrated Dual Thread Reduction Monoaxial Screw (Cannulated) - Dia. (Ø) 3.5 mm to 8.0 mm - Length 20 mm to 100 mm, Fenestrated Dual Thread Reduction Polyaxial Screw (Cannulated) - Dia. (Ø) 3.5 mm to 8.0 mm - Length 20 mm to 100 mm, 0° TLIF Cage (Banana Cage) - Dia. (Ø) 5.0 mm to 15.0 mm - Length 20 mm to 50mm, 0° to 4° PLIF Cage (Bullet Cage) - Dia. (Ø) 5.0 mm to 15.0 mm - Length 20 mm to 50 mm, Cervical Deo Cage -Dia. (Ø) 4.0 mm to 15.0 mm - Length 10 mm to 20 mm,Cervical Fusion Cage - - Dia. (Ø) 4.0 mm to 15.0 mm - Length 10 mm to 20mm, Cervical Cage With Plate - Dia. (Ø) 4.0 mm to 15.0 mm - Length 10 mm to 20 mm, Cervical Bone Screw Self Drilling & Tapping - Dia. (Ø) 3.0 mm to 5.0 mm - Length 10 mm to 100 mm, Cervical Revision Bone Screw Self Drilling & Tapping - Dia. (Ø) 3.7 mm to 4.8 mm - Length 10 mm to 100 mm, LCP Cervical Cage Self Drilling & Tapping - Dia. (Ø) 3.5 mm to 4.5 mm - Length 10 mm to 40 mm, Expandable Cage - Dia. (Ø) 10.0 mm to 30.0 mm - Length 10 mm to 80 mm, Expandable Jack Cage Without Plate or With Plate - Dia. (Ø) 10.0 mm to 20.0 mm - Length 20 mm to 80 mm,Mash/Eco Cage Diamond or Round Cut Plate - - Dia. (Ø) 10.0 mm to 20.0 mm - Length 20 mm to 200 mm, Anterior Cervical Plate - Dia. (Ø) 3.0 mm to 5.0 mm - Length 20 mm to 100 mm, Posterior Multiaxial Cervical Screw (Lateral Mass Screw) - Dia. (Ø) 3.5 mm to 4.5 mm - Length 10 mm to 100mm, Cervical Rod For Latera Mass - Dia. (Ø) 3.0 mm to 5.0 mm - Length 20 mm to 500mm, Cervical Lateral Connector - Dia. (Ø) 3.0 mm to 4.0 mm - Length 10 mm to 60mm, Spine Combi Rod - Dia. (Ø) 3.0 mm to 6.0 mm - Length 25 mm to 500mm, Spine Bone Screw - Dia. (Ø) 3.0 mm to 5.0 mm - Length 08 mm to 50 mm, Occipital T Plate - Dia. (Ø) 3.5 mm to 4.5 mm - Length Small, Medium & Large,Occipital Y Plate - - Dia. (Ø) 3.5 mm to 4.5 mm - Length Small, Medium & Large, LCP Occipital Screw Plate - Dia. (Ø) 3.5 mm to 4.5 mm - Length 08 mm to

	20 mm, Spinal Hook - Dia. (Ø) 5.0 mm to 6.0 mm - Length 20 mm to 30mm, Spine Staple - Dia. (Ø) 10.0 mm to 15.0 mm - Length 15 mm to 30mm, Minimally Invasive Spine (Mis) Poly Axial Screw Dia. (Ø) 4.0 mm to 10.0 mm - Length 15 mm to 80mm, Spine Screw - Dia. (Ø) 3.5 mm to 10.0 mm - Length 20 mm to 100mm, Spine Cage - Dia. (Ø) 4.0 mm to 14.0 mm - Length 10 mm to 40 mm , OLIF Cage - Dia. (Ø) 4.0 mm to 15.0 mm - Length 10 mm to 50 mm,Cervical Cage - - Dia. (Ø) 4.0 mm to 15.0 mm - Length 10 mm to 20 mm, Pedicle Hook - Dia. (Ø) 10.0 mm to 15.0 mm - Length 21 mm to 30 mm, Occipital Rod Plate - Dia. (Ø) 3.0 mm to 4.0 mm - Length 3 Holes to 10 Holes, Lift Expandable Interbody TLIF Cage - Lift Interbody Expandable PLIF Cage, Expandable Spine Cage, Expandable Lift Expandable Cage, ALIF Cage, OLIF Cage, DLIF Cage, LLIF Cage, M.I.S Endoscopic Cage, M.I.S Fen Screw, M.I.S Screw, Jamshedi Niddle, Ollif Cages. 17. Equivalence to predicte device :Yes
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- 1. Generic Name :**Spinal Implant (Titanium)
- 2. Brand Name(if registered under the Trade Marks Act, 1999) :**NISHTHA MEDIQUIP
- 3. Notified Category :**Orthopaedic Implants
- 4. Class of Medical Device :**Class C
- 5. Shelflife :**NIL
- 6. Sterilization:**Non-Sterilized
- 7. Contains Drugs:**No
- 8. Medical Device Grouping Category :** Family
- 9. Grouping Description:** NIL
- 10. Intended Use :**Spinal implants are used to stabilize the unstable spine caused by trauma or by slipped vertebrae (spondylolisthesis) originating from degenerative intervertebral disks. Surgical stabilization can be achieved from either the anterior or posterior approach.
- 11. Product Description:** Spinal Implant consists of rods or plates, anterior screws, pedicle screws, sacral/iliac screws, hooks, connectors, crosslinks, fasteners. These spinal Implants are single use device supplied Non-sterile. The devices are available in different sizes.
- 12. Material of Construction:** TITANIUM
- 13. Dimension:** Various Dimensions
- 14. Storage Condition:** Not Applicable
- 14. Pack Size:** Single Unit per Pack
- 15. Accessory:** NIL
- 16. Model No. :**Monoaxial Screw - - Dia. (Ø) 3.5 mm to 8.0 mm - Length 20 mm to 100mm, Polyaxial Screw - Dia. (Ø) 3.5 mm to 8.0 mm - Length 20 mm to 100mm,Reduction Monoaxial Screw - - Dia. (Ø) 3.5 mm to 8.0 mm - Length 20 mm to 100mm, Reduction Polyaxial Screw - Dia. (Ø) 3.5 mm to 8.0 mm - Length 20 mm to 100mm, Dual Thread Monoaxial Screw - Dia. (Ø) 3.5 mm to 8.0 mm - Length 20 mm to 100mm, Dual Thread Polyaxial Screw - Dia. (Ø) 3.5 mm to 8.0 mm - Length 20 mm to 100mm, Dual Thread Reduction Monoaxial Screw - Dia. (Ø) 3.5 mm to 8.0 mm - Length 20 mm to 100mm, Dual Thread Reduction Polyaxial Screw - Dia. (Ø) 3.5 mm to 8.0 mm - Length 20 mm to 100mm, Spinal Rod - - Dia. (Ø) 3.0 mm to 7.0 mm - Length 20 mm to 600 mm, Spinal Connector Rod - Dia. (Ø) 3.4 mm to 5.0 mm - Length 50 mm to 350mm, Domino Connector - Dia. (Ø) 5.0 mm to 7.0 mm - Length 20 mm to 40 mm, Spinal Transverse Connector - Dia. (Ø) 4.0 mm to 7.0 mm - Length 10 mm to 40 mm, Lateral / Elia Connector - Dia. (Ø) 4.0 mm to 7.0 mm - Length 10 mm to 50 mm, Pedical hook(diff. size) , Lamina hook (diff. size) , Lamina hook wide blade (diff. size) , Lamina hook narrow blade (diff. size) , occipital hook (diff. size) , occifix plate size : 50 mm to 250mm , occifix rod Size : 50 mm to 250 mm , triangle connector size : 3.0 mm to 6.0 mm,spinal Crosslink Connector - - Dia. (Ø) 4.0 mm to 7.0 mm - Length 20 mm to 200 mm, Fenestrated Monoaxial Screw (Cannulated) - Dia. (Ø) 3.5 mm to 8.0 mm - Length 20 mm to 100 mm, Fenestrated Polyaxial Screw (Cannulated) - Dia. (Ø) 3.5 mm to 8.0 mm - Length 20 mm to 100 mm, Fenestrated Reduction Monoaxial Screw (Cannulated)- Dia. (Ø) 3.5 mm to 8.0 mm - Length 20 mm to 100 mm, Fenestrated Reduction Polyaxial Screw (Cannulated) - Dia. (Ø) 3.5 mm to 8.0 mm -Length 20 mm to 100 mm, Fenestrated Dual Thread Monoaxial Screw (Cannulated) - Dia. (Ø) 3.5 mm to 8.0 mm - Length 20 mm to 100 mm,Fenestrated Dual Thread Polyaxial Screw (Cannulated) - - Dia. (Ø) 3.5 mm to 8.0 mm - Length 20 mm to 100 mm, Fenestrated Dual Thread Reduction Monoaxial Screw (Cannulated) - Dia. (Ø) 3.5 mm to 8.0 mm - Length 20 mm to 100 mm, Fenestrated Dual Thread Reduction Polyaxial Screw (Cannulated) - Dia. (Ø) 3.5 mm to 8.0 mm - Length 20 mm to 100 mm, 0° TLIF Cage (Banana Cage) - Dia. (Ø) 5.0 mm to 15.0 mm - Length 20 mm to 50mm, 0° to 4° PLIF Cage (Bullet Cage) - Dia. (Ø) 5.0 mm to 15.0 mm - Length 20 mm to 50 mm,Cervical Deo Cage - -Dia. (Ø) 4.0 mm to 15.0 mm - Length 10 mm to 20 mm, Cervical Fusion Cage - Dia. (Ø) 4.0 mm to 15.0 mm - Length 10 mm to 20mm, Cervical Cage With Plate - Dia. (Ø) 4.0 mm to 15.0 mm - Length 10 mm to 20 mm, Cervical Bone Screw Self Drilling & Tapping - Dia. (Ø) 3.0 mm to 5.0 mm - Length 10 mm to 100 mm, Cervical Revision Bone Screw Self Drilling & Tapping - Dia. (Ø) 3.7 mm to 4.8 mm - Length 10 mm to 100 mm, LCP Cervical Cage Self Drilling & Tapping - Dia. (Ø) 3.5 mm to 4.5 mm - Length 10 mm to 40 mm, Expandable Cage - Dia. (Ø) 10.0 mm to 30.0 mm - Length 10 mm to 80 mm, Expandable Jack Cage Without Plate or With Plate - Dia. (Ø) 10.0 mm to 20.0 mm - Length 20 mm to 80 mm,Mash/Eco Cage Diamond or Round Cut Plate - - Dia. (Ø) 10.0 mm to 20.0 mm - Length 20 mm to 200 mm, Anterior Cervical Plate - Dia. (Ø) 3.0 mm to 5.0 mm - Length 20 mm to 100 mm, Posterior Multiaxial Cervical Screw (Lateral Mass Screw) - Dia. (Ø) 3.5 mm to 4.5 mm - Length 10 mm to 100mm, Cervical Rod For Latera Mass - Dia. (Ø) 3.0 mm to 5.0 mm - Length 20 mm to 500mm, Cervical Lateral Connector - Dia. (Ø) 3.0 mm to 4.0 mm - Length 10 mm to 60mm, Spine Combi Rod - Dia. (Ø) 3.0 mm to 6.0 mm - Length 25 mm to 500mm, Spine Bone Screw - Dia. (Ø) 3.0 mm to 5.0 mm - Length 08 mm to 50 mm, Occipital T Plate - Dia. (Ø) 3.5 mm to 4.5 mm - Length Small, Medium & Large, Occipital Y Plate - Dia. (Ø) 3.5 mm to 4.5 mm - Length Small, Medium & Large,LCP Occipital Screw Plate - - Dia. (Ø) 3.5 mm to 4.5 mm - Length 08 mm to

	20 mm, Spinal Hook - Dia. (Ø) 5.0 mm to 6.0 mm - Length 20 mm to 30mm, Spine Staple - Dia. (Ø) 10.0 mm to 15.0 mm - Length 15 mm to 30mm, Minimally Invasive Spine (Mis) Poly Axial Screw Dia. (Ø) 4.0 mm to 10.0 mm - Length 15 mm to 80mm, Spine Screw - Dia. (Ø) 3.5 mm to 10.0 mm - Length 20 mm to 100mm, Spine Cage - Dia. (Ø) 4.0 mm to 14.0 mm - Length 10 mm to 40 mm , OLIF Cage - Dia. (Ø) 4.0 mm to 15.0 mm - Length 10 mm to 50 mm, Cervical Cage - Dia. (Ø) 4.0 mm to 15.0 mm - Length 10 mm to 20 mm, Pedicle Hook - Dia. (Ø) 10.0 mm to 15.0 mm - Length 21 mm to 30 mm, Occipital Rod Plate - - Dia. (Ø) 3.0 mm to 4.0 mm - Length 3 Holes to 10 Holes, Lift Expandable Interbody TLIF Cage - Lift Interbody Expandable PLIF Cage, Expandable Spine Cage, Expandable Lift Expandable Cage, ALIF Cage, OLIF Cage, DLIF Cage, LLIF Cage, M.I.S Endoscopic Cage, M.I.S Fen Screw, M.I.S Screw, Jamshedi Niddle, Ollif Cages. 17. Equivalence to predicate device :Yes
13	1. Generic Name :Crano-Maxillofacial Implant (Titanium) 2. Brand Name(if registered under the Trade Marks Act, 1999) :NISHTHA MEDIQUIP 3. Notified Category :Orthopaedic Implants 4. Class of Medical Device :Class C 5. Shelflife :NIL 6. Sterilization:Non-Sterilized 7. Contains Drugs:No 8. Medical Device Grouping Category : Family 9. Grouping Description: NIL 10. Intended Use :Maxillofacial Implant is indicated for the augmentation and/or restoration of bony and/or soft tissue deformities in the cranial and craniofacial skeleton comprised of the mouth, jaws, face, neck, and skull. 11. Product Description: The Maxillofacial Implants are single use device supplied Non-sterile. The devices are available in different sizes. 12. Material of Construction: TITANIUM 13. Dimension: Various Dimensions 14. Storage Condition: Not Applicable 14. Pack Size: Single Unit per Pack 15. Accessory: NIL 16. Model No. :Straight plate without gap - (1.5mm ,2.0mm - ,2.5mm) - ,Straight Pate with gap (1.5mm - ,2.0mm - ,2.5mm) - ,Mini L Plate With Gap 90° (Right & Left) (1.5 mm - ,2.0mm - ,2.5mm) - ,Mini L Plate Without Gap 90° (Right & Left) - (1.5mm ,2.0mm - ,2.5 mm) - ,Mini L Plate With Gap 120° (Right & Left) (1.5mm - ,2.0mm - ,2.5mm) - ,Mini L Plate Without Gap 120° (Right & Left) (1.5mm - ,2.0mm - ,2.5mm) - ,Mini T Plate With Gap (1.5 mm - ,2.0mm - ,2.5mm) - ,Mini T Plate Without Gap (1.5mm - ,2.0mm - ,2.5mm) - ,Mini I Shape Plate (1.5mm - ,2.0mm - ,2.5mm) - ,Mini Y Shape Small Plate (1.5mm - ,2.0mm - ,2.5 mm) - ,Mini Y Shape Large Plate (1.5mm - ,2.0mm - ,2.5mm) - ,Mini Double 'Y' Shape Plate (1.5 mm - ,2.0mm - ,2.5mm) - ,Mini X Shape Plate (1.5mm - ,2.0mm - ,2.5mm) - ,Mini Z Shape Plate (Right & Left) (1.5mm - ,2.0mm - ,2.5mm) - ,Mini H Shape Plate (1.5mm - ,2.0 mm - ,2.5mm) - ,Mini Nose Plate Y Shape (1.5mm - ,2.0mm) - ,Mini Nose Plate H Shape (1.5 mm - ,2.0mm) - ,Mini Orbital Plate With Gap - (1.5mm ,2.0mm - ,2.5mm) - ,Mini Orbital Plate Without Gap (1.5mm - ,2.0mm - ,2.5mm) - ,Orbital Floor Plates (Small - ,Medium - , Large) - ,Mini Burr Hole Plate (1.5mm - ,2.0mm) - ,Mini Burr Hole Plate Pre bend(1.6mm - ,2.0mm) - ,Mini Chin Plate (1.5mm- 2x2) (2.0mm 2x2) (2.0mm 2x3) - ,Mini 3D Square Plate (1.5mm - ,2.0mm - ,2.5 mm) - ,Mini 3D Rectangular Plate (1.5mm - ,2.0mm - ,2.5mm) - , Wire Mesh Plane (1.5mm - ,2.0mm) - ,Wire Mesh Pre bend (1.5mm - ,2.0mm) - ,Easy Mesh Plate Plane (1.5mm - ,2.0 mm) - ,Easy Mesh Plate Pre bend (1.5mm - ,2.0mm) - ,Mini Straight Reconstruction Plate (2.7mm) (thickness 2.0mm) - ,T.M.J. Condylar Plate (Right & Left) - (2.7mm) ,T.M.J. Condylar with Reconstruction Angular Plate (Right & Left) (2.7mm) - , Mini Angular Reconstruction Plate (Right & Left) (2.7mm) - ,Mini Double Angled Reconstruction Plate - ,Mini Full Mandibular Reconstruction Plate - ,Mestroid Plate (1.5mm) - ,Trapezoid Condyle Plates (2.0mm) - ,Twisted Plates (Right & Left) (2.0mm) - ,Grid Plates (2.0mm) - ,Shtrut Plate (2.0mm). - 17. Equivalence to predicate device :Yes

14	1. Generic Name :Hip Replacement System (Stainless Steel) 2. Brand Name(if registered under the Trade Marks Act, 1999) :NISHTHA MEDIQUIP 3. Notified Category :Orthopaedic Implants 4. Class of Medical Device :Class D 5. Shelflife :NIL 6. Sterilization:Non-Sterilized 7. Contains Drugs:No 8. Medical Device Grouping Category : System 9. Grouping Description: NIL 10. Intended Use :Hip Replacement System is intended for use in total hip arthroplasty. Total hip arthroplasty is intended to provide patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is an evidence of sufficient sound bone to fix and support the components. 11. Product Description: Hip Replacement System consists of femoral heads and femoral stems. The femoral heads and femoral stems are single use device supplied Non-sterile. The devices are available in different sizes. 12. Material of Construction: STAINLESS STEEL 316L 13. Dimension: Various Dimensions 14. Storage Condition: Not Applicable 14. Pack Size: Single Unit per Pack 15. Accessory: NIL 16. Model No. :Bipolar Prosthesis - Fenestrated / Non-Fenestrated - - Dia. (Ø) 37.0 mm to 65.0 mm Stem Sizes: Small, Medium, Large & Extra Large,Austin Moore Hip Prosthesis (Amp) - Dia. (Ø) 37.0 mm to 65.0 mm Stem Sizes: Small, Medium, Large & Extra Large, Thompson Hip Prosthesis - - Dia. (Ø) 37.0 mm to 65.0 mm Stem Sizes: Small, Medium, Large & Extra Large, Modular Bipolar Stem Cemented Stem Sizes: Small, Medium, Large & Extra Large, Modular Bipolar V Stem Cemented Stem Sizes: Small, Medium, Large & Extra Large, Modular Bipolar Stem Un-Cemented Stem Sizes: Small, Medium, Large & Extra Large, Modular Bipolar Serrated Stem Un-Cemented Stem Sizes - Small, Medium, Large & Extra Large, Modular Bipolar Inner Head - Dia. (Ø) 22.0 mm to 28.0 mm - Sizes (+8, +3, 0, -2), Hip Prosthesis Stem - Stem Sizes: Small, Medium, Large & Extra Large. 17. Equivalence to predicate device :Yes
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5. Whether substantial equivalence to a predicate device is claimed: refer the table

6. Fee paid on 29-AUG-2025, INR 65000.00 receipt/challan/transaction id 2908250055657.

7. I have enclosed the documents as specified in the Fourth Schedule of Medical Devices Rules, 2017.

8. I hereby state and undertake that:

(i) the manufacturing site is ready for audit or shall be ready for audit on _____ in accordance with the requirements of Medical Devices Rules, 2017.

(ii) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940(23 of 1940) and the Medical Devices Rules, 2017.

Place:

Signature

Date: 02-Jun-26

(Name and Designation)