



C E R T I F I C A T E

FULL QUALITY ASSURANCE SYSTEM APPROVAL EC CERTIFICATE

n. 0068/QCO-DM/259-2020

according to Annex II of Directive 93/42/EEC on Medical Devices as amended

MTIC Intercert hereby declares that an examination of the under mentioned Full Quality Assurance System has been carried out following the requirements of the legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on Medical Devices. **MTIC Intercert certifies that the Full Quality Assurance System conforms with the relevant provisions of the aforementioned legislation. The validity of this certificate is subjected to the positive result of required surveillance audits.**

MANUFACTURER:

GPC Medical Limited

Head office: GPC Square, M-Block, DDA LSC, Vikas Puri, New Delhi-110018 (INDIA)

Factory: Plot Number C-3, Sector B-1, UPSIDC, Trans Delhi Signature City, 201102, Loni, Ghaziabad, Uttar Pradesh (INDIA)

DEVICE/S:

Orthopaedic implants

MODEL/S:

- | | | |
|---------------------------|----------------------------------|---|
| 1. Metallic Bone Plates | 2. Metallic Bone Screws | 3. Metallic Nailing System |
| 4. Metallic Spinal System | 5. Metallic Pins, Wires, Staples | 6. Metallic & Carbon fiber, External Fixators |

see list of all models in annex 1


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This certificate is also made of n. 1 annex of n. 13 pages


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1. Metallic Bone Plates


✓ Locking & Non-locking DHS Plate (Long & Short Barrel), 4.5 mm- 125°, 130°, 135°, 140°, 145°, 150°	2 Holes- 20 Holes
✓ Locking & Non Locking Variable Angle DHS Plate	2 Holes- 20 Holes
✓ Locking & Non locking Double Angle DHS Plate	2 Holes- 20 Holes
✓ Locking & Non-locking Pediatric DHS Plate	2 Holes- 12 Holes
✓ Locking & Non-locking DCS Barrel Plate 95°	6 Holes- 18 Holes
✓ Trochanter Stabilizing Plate, 4.5 mm	---
✓ Cobra Head Plate, 4.5 mm	7 Holes- 16 Holes
✓ Spoon Plate, 4.5 mm	5 Holes- 6 Holes
✓ Jewett Nail Plate, 4.5 mm- 130°, 135°	4 Holes- 18 Holes
✓ Locking & Non-locking Angled Blade Plate, 4.5 mm- 90°, 100°, 120°, 130°	5 Holes- 18 Holes
✓ Locking & Non-locking Condylar Blade Plate 95°, 4.5 mm	5 Holes- 20 Holes
✓ Locking & Non-locking Condylar Buttress Plate, 4.5 mm	6 Holes- 16 Holes
✓ Locking & Non-locking Proximal Femur Plate- Medial & Lateral	6 Holes- 18 Holes
✓ Locking & Non-locking Proximal femur Hook Plate	6 Holes- 18 Holes
✓ Locking & Non-locking Distal Femur Plate, 4.5 mm- Medial & Lateral	5 Holes- 18 Holes
✓ Locking & Non-locking Proximal Tibia Plate, 4.5 mm & 3.5 mm- Medial & Lateral	4 Holes- 18 Holes
✓ Locking & Non-locking Posterior Medial Proximal Tibia Plate, 3.5 mm	4 Holes- 18 Holes
✓ Locking & Non-locking Distal Tibia Plate, 4.5 mm & 3.5 mm- Medial & Lateral	4 Holes- 18 Holes
✓ Locking & Non-locking Medial Distal Tibia Plate, 3.5 mm with & without tab	4 Holes- 18 Holes
✓ Locking & Non-locking Anterolateral Distal Tibia Plate, 3.5 mm	4 Holes- 18 Holes
✓ Locking & Non-locking Tibial Osteotomy, 4.5 mm	2 Holes- 14 Holes
✓ Locking & Non-locking Distal Lateral Fibula Plate, 3.5 mm	3 Holes- 15 Holes
✓ Locking & Non-locking Cloverleaf Plate, 3.5 mm	3 Holes- 16 Holes
✓ Locking & Non-locking T-Plate (with 3 Head Holes & Head Holes)- 4.5 mm, 3.5 mm	3 Holes- 16 Holes
✓ Locking & Non-locking L-Buttress Plate, 4.5 mm	3 Holes- 12 Holes
✓ Locking Compression plate, 1.5 mm, 2.0 mm, 2.4 mm, 2.7 mm, 3.5 mm, 3.5 Borad, 4.5 mm, 4.5 mm Broad	2 Holes- 22 Holes
✓ Dynamic Compression plate, 1.5 mm, 2.0 mm, 2.4 mm, 2.7 mm, 3.5 mm, 3.5 Borad, 4.5 mm, 4.5 mm Broad	2 Holes- 22 Holes
✓ Limited Contact Dynamic Compression Plate, 1.5 mm, 2.0 mm, 2.4 mm, 2.7 mm, 3.5 mm	2 Holes- 22 Holes
✓ Limited Contact Dynamic Compression Plate, 4.5 mm- Narrow	2 Holes- 22 Holes

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1. Metallic Bone Plates

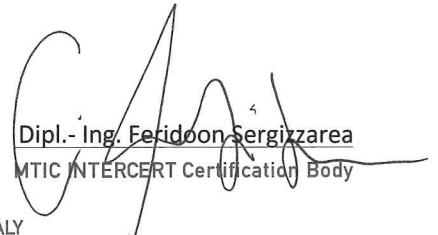
✓ Limited Contact Dynamic Compression Plate, 4.5 mm- Broad	2 Holes- 22 Holes
✓ Locking & Non-locking Reconstruction Plate, Straight & Curved- 2.7 mm, 3.5 mm, 4.5 mm	2 Holes- 22 Holes
✓ Locking & Non-locking One Third Tubular Plate with collar	2 Holes- 14 Holes
✓ Locking & Non-locking One Third Tubular Plate without collar	2 Holes- 14 Holes
✓ Locking & Non-locking Quarter Tubular Plate	3 Holes- 12 Holes
✓ Locking & Non-locking Semi Tubular Plate	2 Holes- 14 Holes
✓ Locking & Non-locking Clavicle S-Plate	6 Holes- 8 Holes
✓ Locking & Non-locking Clavicle Hook Plate, 3.5 mm- 12 mm, 15 mm, 18 mm depth	6 Holes- 8 Holes
✓ Locking & Non-locking Clavicle Plate with Lateral Extension, 2.7 mm/3.5 mm	6 Holes- 8 Holes
✓ Locking & Non-locking Lecestre Plate, 3.5 mm	5 Holes- 13 Holes
✓ Locking & Non-locking Proximal Humerus Plate, 3.5 mm	3 Holes- 12 Holes
✓ Locking & Non-locking Philos Plate, 3.5 mm- Long & Short	3 Holes- 12 Holes
✓ Locking & Non-locking Olecranon Plate, 2.7/3.5 mm	6 Holes- 12 Holes
✓ Sherman Plate, 3.5 mm	2 Holes- 8 Holes
✓ Locking & Non-locking Y-Reconstruction Plate, 3.5 mm/4.5 mm	6 Holes- 12 Holes
✓ Locking & Non-locking Distal Humerus Plate, 2.7 mm/3.5 mm	3 Holes- 14 Holes
✓ Locking & Non-locking Medial Distal Humerus Plate, 2.7 mm/3.5 mm	3 Holes- 14 Holes
✓ Locking & Non-locking Distal Humerus Plate with Lateral Support, 2.7 mm/3.5 mm	3 Holes- 14 Holes
✓ Locking & Non-locking Distal Humerus Plate, Extraarticular, 3.5 mm	5 Holes- 15 Holes
✓ Locking & Non-locking Proximal Radius Plate, 2.4 mm	2 Holes- 6 Holes
✓ Locking & Non-locking Hook Plate, 3.5 mm	6 Holes- 8 Holes
✓ Locking & Non-locking Straight Plate, 1.5 mm, 2.0 mm, 2.4 mm, 2.7 mm, 3.5 mm	4 Holes- 20 Holes
✓ Eight Plate/Growth Plate	12 mm- 16 mm
✓ Locking & Non-locking Osteotomy Plate	2 Holes- 14 Holes
✓ Locking & Non-locking Distal Radius Buttress Plate, 2.4 mm	2 Holes- 6 Holes
✓ Locking & Non-locking Volar Distal radius Plate- Extraarticular, 2.4 mm	2 Holes- 6 Holes
✓ Locking & Non-locking Two Column Volar Distal Radius Plate, 2.4 mm	2 Holes- 6 Holes
✓ Locking & Non-locking Dorsal Distal Radius Plate, 2.4 mm- L-Plate	2 Holes- 6 Holes
✓ Locking & Non-locking Dorsal Distal Radius Plate, 2.4 mm- T-Plate	2 Holes- 6 Holes
✓ Locking & Non-locking Calcaneal Plate, 3.5 mm	60 mm- 76 mm
✓ Locking & Non-locking Metaphyseal Plate, 3.5 mm	3 Holes- 14 Holes
✓ Locking & Non-locking Pilon Plate, 3.5 mm	7 Holes- 9 Holes

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✓ Locking & Non-locking Adaption Plate, 1.5 mm, 2.4 mm, 2.7 mm	4 Holes- 12 Holes
✓ Locking & Non-locking Condylar Plate, 1.5 mm, 2.4 mm, 2.7 mm	3 Holes- 8 Holes
✓ Locking & Non-locking Strut Plate	3 Holes- 4 Holes
✓ Locking & Non-locking Extended H-Plate, 1.5 mm, 2.0 ,,	2 Holes- 8 Holes
✓ Locking & Non-locking T-Plate with 3 Head Holes, 1.5 mm, 2.0 mm, 2.4 mm	4 Holes- 8 Holes
✓ Locking & Non-locking T-Plate with 4 Head Holes, 1.5 mm, 2.0 mm, 2.4 mm	4 Holes- 8 Holes
✓ Locking & Non-locking Y-Plate, 1.5 mm, 2.0 mm, 2.4 mm	3 Holes- 8 Holes
✓ Locking & Non-locking L-Plate, 1.5 mm, 2.0 mm, 2.4 mm, 2.7 mm	2 Holes- 4 Holes
✓ Locking & Non-locking Oblique L-Plate, 1.5 mm, 2.0 mm, 2.4 mm, 2.7 mm	2 Holes- 4 Holes
✓ Locking & Non-locking Nose Plate	1.5, 2.0, 2.5 mm
✓ Locking & Non-locking H-Plate	2 Holes- 8 Holes
✓ Locking & Non-locking Z-Plate	8 mm- 16 mm
✓ Locking & Non-locking Orbital Plate	4 Holes- 8 Holes
✓ Locking & Non-locking Orbital Floor Plate- Butterfly	0.4 - 0.6 mm
✓ Locking & Non-locking Orbital Floor Plate- Round	0.4 - 0.6 mm
✓ Mesh Plate	40 mm- 100 mm
✓ 3D Square Plate	4 Holes- 13 mm- 17 mm
✓ I-shape Plate	6 mm- 9 mm
✓ Chin Plate- Straight & Curved	4 mm- 10 mm
✓ Arch Bar	---
✓ Arthrodesis Plate	6 Holes- 8 Holes
✓ Locking & Non-locking Straight Plate with bridge	4 Holes- 8 Holes
✓ Burr Hole Plate	12 mm- 25 mm
✓ Locking & Non-locking Distal Ulna Plate	40 mm- 70 mm
✓ Cobra Plate	4- 10 holes
✓ Locking & Non-locking Styloid Plate	4- 10 holes
✓ Variable Angle Distal Radius Plate	2 Holes- 6 Holes
✓ Variable Angle Condylar Plate	6 Holes- 18 Holes
✓ Wrist Fusion Plate	4 Holes- 10 Holes
✓ Locking & Non-locking Distal Femur Osteotomy Plate	4 Holes- 12 Holes
✓ Fork Plate	---

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2. Metallic Bone Screws

✓ Cortex Screw 4.5 mm, 3.5 mm, 2.7 mm, 2.4 mm, 2.0 mm, 1.5 mm, 1.3 mm, 1.0 mm	Length 6 mm to 110 mm
✓ Cancellous Screw 6.5 mm, 5.5 mm, 5.0 mm, 4.0 mm, 3.5 mm, 3.0 mm	Length 10 mm to 140 mm
✓ Cannulated Cancellous Screw 7.3 mm, 7.0 mm, 6.5 mm, 5.0 mm, 4.5 mm, 4.0 mm, 3.0 mm	Length 10 mm to 150 mm
✓ Cannulated Conical Screw 7.3 mm, 5.0 mm, 3.5 mm	Length 20 mm to 150 mm
✓ Cannulated Conical Screw 5.0 mm	Length 20 mm to 150 mm
✓ Cannulated Conical Screw 3.5 mm	Length 20 mm to 150 mm
✓ Malleolar Screw 4.5 mm, 3.5 mm	Length 25 mm to 100 mm
✓ DHS/DCS Lag Screw- Adult/Paediatric	Length 50 mm to 145 mm
✓ DHS Compression Screw/Blocked Screw	---
✓ Shaft Screw 4.5 mm, 3.5 mm	Length 22 mm to 110 mm
✓ Emergency Screw 2.7 mm, 2.3 mm, 2.4 mm, 3.2 mm, 3.5 mm	Length 4 mm to 40 mm
✓ Cancellous Traction Screw 6.5 mm	Length 25 mm to 130 mm
✓ ACL/PCL Interference Screw 6.0 mm, 7.0 mm, 8.0 mm, 9.0 mm, 10.0 mm, 11.0 mm	Length 20 mm to 40 mm
✓ Peek ACL Screw	Length 20 mm to 40 mm
✓ Cannulated Herbert Screw/Headless Compression Screw 6.5 mm, 5.0 mm, 4.5 mm, 3.5 mm, 3.0 mm, 2.7 mm, 2.4 mm, 2.0 mm, 1.5 mm	Length 6 mm to 120 mm
✓ Locking Compression Screw 5.0 mm, 3.5 mm, 2.7 mm, 2.4 mm, 2.0 mm, 1.5 mm, 1.0 mm	Length 6 mm to 100 mm
✓ Locking Cancellous Screw 6.5 mm, 5.0 mm, 3.5 mm	Length 10 mm to 120 mm
✓ Washer	Small, Large
✓ Variable Angle Locking Screw 5.0 mm, 3.5 mm, 2.7 mm, 2.4 mm	Length 6 mm to 80 mm
✓ Variable Angle Locking Buttress Screw 1.8 mm, 2.4 mm	Length 6 mm to 40 mm
✓ Cross Slotted Screw 2.5 mm, 2.4 mm, 2.0 mm, 1.5 mm, 1.2 mm, 1.0 mm	Length 4 mm to 20 mm
✓ Nut Hexagonal	---
✓ Spiked Washer	---
✓ Space Washer	---
✓ Endo Button with, without & adjustable loop	Length 15 mm to 25 mm
✓ Suture Anchor Screw	Dia. 2.0 mm to 5.0 mm
✓ Cannulated & Non-cannulated Drill Bits	Dia. 0.4 mm to 17 mm

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3. Metallic Nailing System

✓ Tibial Nails Dia. 8 mm, 9 mm, 10 mm, 11 mm, 12 mm, 13 mm, 14 mm	Length 22cm to 44cm
✓ Unreamed Tibial Nail Dia. 8 mm, 9 mm, 10 mm, 11 mm, 12 mm, 13 mm, 14 mm	Length 26cm to 40cm
✓ Reamed Tibial Nail, Distal Tip Dia. 8 mm, 9 mm, 10 mm, 11 mm, 12 mm, 13 mm, 14 mm	Length 26cm to 40cm
✓ Multiangle Locking Tibia Nail Dia. 8 mm, 9 mm, 10 mm	Length 26cm to 40cm
✓ Sign Tibia Nail Dia. 8 mm, 9 mm	Length 22cm to 44cm
✓ Femoral Nails Dia. 9 mm, 10 mm, 11 mm, 12 mm, 13 mm, 14 mm	Length 30cm to 48cm
✓ Unreamed Femoral Nails Dia. 9 mm, 10 mm, 11 mm, 12 mm, 13 mm, 14 mm	Length 30cm to 48 cm
✓ Multi Angle Femoral Nail- Left/Right Dia. 9 mm, 10 mm, 11 mm, 12 mm	Length 28cm to 46 cm
✓ Proximal Hip Stabilizing Nail(Gamma Nail) short Dia. 10 mm, 11 mm, 12 mm	Length 180mm to 220 mm
✓ Proximal Hip Stabilizing Nail (Gamma Nail) Long, Left/Right Dia. 10 mm, 11 mm, 12 mm	Length 300mm to 440 mm
✓ Proximal Femoral Nail Dia. 9 mm, 10 mm, 11 mm, 12 mm	Length 220mm to 260 mm
✓ Proximal Femoral Nail Long- Left/Right-Dia. 9 mm, 10 mm, 11 mm, 12 mm	Length 300mm to 480 mm
✓ Proximal Femoral Nail, Advanced short Dia. 10 mm, 11 mm, 12 mm	Length 170mm to 240 mm
✓ Proximal Femoral Nail, Advanced Long- Left/Right- Dia. 10 mm, 11 mm, 12 mm	Length 340mm to 440 mm
✓ Proximal Hip Stabilizing Nail 3 short - 120° , 125° , 130°-Dia. 10 mm, 11 mm, 12 mm	Length 180mm to 220 mm
✓ Proximal Hip Stabilizing Nail 3 Long, Left/Right- 120° , 125° , 130°-Dia. 10 mm, 11 mm, 12 mm	Length 320mm to 440 mm
✓ Proximal Hip Stabilizing Nail 3 Long- 120° , 125° , 130°-Dia. 11mm Left/Right	Length 320mm to 440 mm
✓ Distal Bolt	Length 30mm to 80 mm
✓ Set Screw	---
✓ End Cap	---
✓ Cephalic Screw	Length 50mm to 130 mm
✓ Locking Bolts 2.9mm, 3.4 mm, 3.9 mm, 4.5 mm, 4.9 mm, 5.9 mm	Length: 16mm to 120 mm
✓ Locking Bolts Cannulated, 6.5 mm, 7.5 mm	Length: 50mm to 130mm
✓ Cannulated Blade Bolt	Length 75mm to 130 mm
✓ Sign Femur Nail Dia. 8 mm, 9 mm	Length 220mm to 440 mm
✓ Supra Condylar Nails/IMSC Nails Dia. 10 mm, 11 mm, 12 mm, 13 mm	Length 15cm to 30 cm
✓ Unreamed Humeral Nails Dia. 6 mm, 7 mm, 8 mm	Length 18 cm to 30cm
✓ Humeral Nail Cannulated Dia. 6 mm, 7 mm, 8 mm	Length 18 cm to 30cm
✓ Reamed Humerus Nail-Omni Dia. 6 mm, 7 mm, 8 mm	Length 18 cm to 32cm
✓ UnReamed Humerus Nail-Omni Dia, 6 mm, 7 mm, 8 mm	Length 18 cm to 32cm
✓ Reconstruction Nail (Left) & Right	Length 34 cm to 48cm

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3. Metallic Nailing System

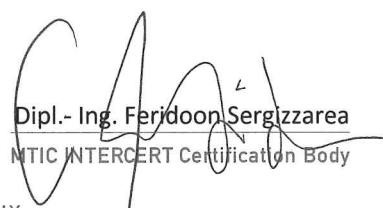
✓ End Cap for Tibial & Femoral Nail	---
✓ End Cap for IMSC Nail	---
✓ End Cap for Reconstruction Nail	---
✓ End Cap for PFN Nail	---
✓ End Cap for Multiangle Tibia/Femur Nail	---
✓ End Cap for Gamma	---
✓ End Cap for PHN3 Nail	---
✓ End Cap for PFA Nail	---
✓ End Cap for Humeral Nail	---
✓ Kuntscher Cloverleaf Nail	Dia: 6mm to 17mm
✓ Ender's Nails	Dia: 3.5 mm to 4.5mm
✓ Rush Nail (Hook Intramedullary)	Dia: 2mm to 6mm
✓ Titanium Elastic Nail	Dia: 2.0mm to 5.0mm
✓ V-Nail	Length:15cm to 48cm
✓ Bend Kuntscher Cloverleaf Nail Tibia	Length: 26cm to 44cm
✓ Square Nail for Radius	Length: 16cm to 30cm
✓ Square Nail for Ulna	Length: 16cm to 30cm
✓ Distal Bolt 6.25mm	Length 30-80mm
✓ End cap for Gamma nail	---

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4. Metallic Spinal System

✓ Mono Axial Screw 4.5 mm, 5.5 mm, 6.5 mm, 7.5 mm	Length 20mm to 60mm
✓ Poly Axial Screw 4.5 mm, 5.5 mm, 6.5 mm, 7.5 mm	Length 20mm to 60mm
✓ Transverse Connector Small, Large	
✓ Rod 3.2 mm -5.8 mm	Length 30mm to 400mm
✓ Mono Axial Reduction Screw 4.5 mm, 5.5 mm, 6.5 mm, 7.5 mm	Length 20mm to 60mm
✓ Poly Axial Reduction Screw 4.5 mm, 5.5 mm, 6.5 mm, 7.5 mm	Length 20mm to 60mm
✓ Lumbar Cage- Titanium size 8 to 10	length 22mm to 26mm
✓ Cervical Cage- Titanium size 4 to 12	length 13mm
✓ Mesh Cage- Titanium Dia., 10mm to 22mm	Height 18mm to 45 mm
✓ Expandable Cage	12mm to 54mm
✓ Lateral Mass Polyaxial Screws Dia. 2.8mm, 3.5 mm, 4.0 mm	Length 10mm to 30mm
✓ Pre-Contoured Rod, Dia. 3.2 mm	---
✓ Tapered Rod For Cervico-Thoracic Fixation	Length 200mm to 250mm
✓ Pre-Bent Cobra Plate Occipital Rod, Length 200 mm	---
✓ Cervico-Thoracic Domino - Rod Holes of 3.2 mm & 6.0 mm - to Connect Lateral Mass Screw & Thoracic Spine	---
✓ Lamina Hook, Narrow & Broad	---
✓ Occipital Clamp, Single Hole, Double Hole	Small, medium, large
✓ Lateral Offset Connector, 3.2 mm	Length 6 mm to 12mm
✓ Occipital Locking Screw, 3.7 mm, 4.2 mm	Length 6 mm to 12mm
✓ Cervical Bladed Cage- PEEK	Size 4mm to 12mm
✓ Anterior Cervical Plates Level 1, Level 2, Level 3	22mm - 71mm
✓ Variable Angle Self Tapping Self Drilling Cancellous Screws, 3.5 mm, 4.0 mm	Length 12mm to 22mm
✓ Low Profile Anterior Cervical Cage	Height 4mm to 12mm
✓ Cervical Spine Locking Screw, 3.0 mm, Hex Head	Length 12mm to 16mm
✓ Iliac Screw System 7.5 mm, 8.0 mm	Length 65mm to 110mm
✓ Polyaxial Pedicle Fenestrated Screw - 4.5 mm, 5.5 mm, 6.5 mm	Length 20mm to 60mm
✓ Mini Plate, 2.0 mm Gap 4 mm - 12 mm	Length 27mm to 35mm
✓ Adaption Plate, 2.0 mm- 20 Holes	---
✓ Self Tapping, Self Drilling Screws, 2.0 mm Cross Slot Head	Length 8mm to 12mm
✓ Transverse Connector (Cross Link)	Small, Medium Large
✓ Notched Spinal Plate	5 holes to 13 holes
✓ Hartsheel Frame 4.0mm, 4.5mm	3 to 11 inch
✓ Inner Screw	
✓ Dorsolumbar Plate	3 holes to 17 holes

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5. Metallic Pins - Wires – Staples

✓ Steinman Pins -Dia 2 mm to 6.5 mm	Length 150 mm to 400 mm
✓ Centrally Threaded Steinmann Pin/ Denham Pin	Dia 2 mm to 6.5 mm
✓ Interface Pins - Dia 1 mm to 6.5 mm	Length 50 mm to 250 mm
✓ Centerface Pins - Dia 1 mm to 6.5 mm	Length 50 mm to 250 mm
✓ Schanz Pins - Dia 2 mm to 6.5 mm	Length 50 mm to 450 mm
✓ Knowles Pin - Dia 2 mm to 6.5 mm	Length 65 mm to 100 mm
✓ Austin Moore Pin	Length 50 mm to 150 mm
✓ Kirschner Wire, Single Ended Trocar/ Double Ended Trocar	Length 100 mm to 500 mm
✓ Orthopaedic Wire	---
✓ Suture Wire/ Soft Wire	Gauge: 16 to 36
✓ Threaded Kirschner Wire -Fully Threaded/ Partially Threaded	Length 150 mm to 225 mm
✓ Cerclage Wire with & without Olive	Length 100 mm to 440 mm
✓ Orthopaedic Guide Wires - Threaded & Non Threaded	---
✓ Ilizarov Wire with/Without Olive	---
✓ Cerclage Wire with Loop	Dia: 0.8 mm to 1.50 mm
✓ Blount Staples	Width 15 mm to 30 mm
✓ Thorny Staples	Width 10 mm to 70 mm
✓ Coventry Staples	Width 5 mm to 15 mm
✓ Wire Fixation Bolts & Nuts	---
✓ Wire Fixation Bolts Slotted	---
✓ Wire Fixation Bolts Cannulated	---
✓ Square Nut	---
✓ Multi Pin Fixation Bolt	---
✓ Conical Washer	---
✓ Spacing Washer	---
✓ Drummond Wire	Gauge: 16 to 26
✓ Gigli Saw Wire - Ordinary and Fine	Length 30 cm to 75 cm
✓ Flexible Wire Cable	Dia 1 mm to 5 mm

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6. Metallic & Carbon fiber

- ✓ AO Tubular Fixator system
 - Double Rod to Pin Clamp, Dia. 5.0 x 11.0 mm, Dia 4.0mmx 8.0mm,
 - Tube to Tube Clamp, Dia. 11.0 x 11.0 mm, 8.0 x 8.0mm,
 - Single Adjustable Clamp / Pin to Rod Clamp, Dia. 5.0 x 11.0 mm, 4.0x8.0 mm,
 - Self Holding Pin to Rod Clamp, Dia. 5.0 x 11.0 mm, 4.0x8.0mm
 - Transverse Clamp, Dia. 5.0 x 11.0 mm
 - Double Adjustable Clamp, S.S., Dia. 5.0 x 11.0 mm
 - Open Clamp, S.S., Dia. 5.0 x 11.0 mm
 - AO Type Schanz Pin / Schanz Screw, Dia 2.0mm-6.5mm, length 50mm-450mm.
 - Connecting Rod / Tubular Rod, Dia 4.0-11mm, Length 60-600mm
 - Curved Connecting Rod, Dia. 4.0-11.0 mm
 - Trapezoidal Curved Connecting Rod, Dia. 4.0-11.0 mm
 - Semi-Circular Curved Rod, Dia. 4.0-11.0 mm
 - Compression / Distraction Rod, Small, Medium, Large
 - Small Clamp, S.S., Dia. 2.5 mm x 4.0 mm, 4.0x4.0mm
 - Hybrid Fixators for Tibia, Femur, Small,Medium, Large
 - Schanz Pin Introducer, Dia 2.0mm-6.0mm

- ✓ Limb Lengthening MonoRail Fixators/Limb Reconstruction system
 - Adult Limb Reconstruction System-Small, Medium, Large, T Type, L type,
 - Paediatric Limb Reconstruction System-Small, Medium, Large, Type T Type, L type,
 - End Clamp, Compression-Distraction Device (CD unit), 60, 80, 100 mm
 - Swivel Clamp
 - Dummy Clamp
 - Multiplanar clamp
 - Hinge Clamp
 - Garches T Clamp
 - Hexagonal Bolt
 - Sandwich Clamp
 - Graduated Swivel Clamp
 - Mini Rail Horizontal Axis Fixator
 - Mini Rail Lengtheners Fixator

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C E R T I F I C A T E

ANNEX No. 1 TO THE FULL QUALITY ASSURANCE SYSTEM APPROVAL EC CERTIFICATE

n. 0068/QCO-DM/259-2020

according to Annex II of Directive 93/42/EEC on Medical Devices as amended

6. Metallic & Carbon fiber

- | | | |
|---|---|--|
| ✓ | Dynamic External Fixator/Multi axial External Fixator | Straight Dynamic External Fixator - Small, Medium, Large
T Type Dynamic External Fixator- Small, Medium, Large
L Type Dynamic External Fixator - Small, Large
Dynamic External Fixator Wrist
Petrochantric Fixator
Elbow Fixator
Dynamic External Fixator Pelvic: Type A, Type B
Dynamic External Fixator - Knee Joint
Wrist External Fixator in PEEK
Ankle Joint External Fixator in PEEK
Tibia External Fixator in PEEK
High Tibial Osteotomy Fixator |
| ✓ | Hoffman I Fixator | Pin to Rod Clamp, 2.0mm-8.0mm
Periarticular Pin Clamp, 2.0-8.0 mm
4-hole Coupling, 5-hole coupling, 8- hole coupling
Pin to Rod Mini Clamp, Dia. 2.0-8.0mm
Rod to Rod Mini Clamp, Dia. 2.0-8.0 mm
Post-30 Degree, Straight, Dia 4.0-11.0mm
Self-drilling Schanz Pins, Dia 2.0-6.0 mm, Length 50-450mm
Elbow Joint Mobilizer, S.S., Dia. 5.0 mm
Wrist Joint Mobilizer, S.S., Dia. 5.0 mm
Stabilization / Reduction Wrench, Thumb wheel, Hand Drill
Tube to Rod Clamp, Dia. 8.0 mm x 20.0 mm
Ankle Joint Mobilizer, Dia. 8.0-11.0 mm
Knee Joint Mobilizer, S.S., Dia. 8.0mm-11.0mm
Semi-Circular Curved Connecting Rod, S.S.
Compression/Distracton tube |

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6. Metallic & Carbon fiber

✓ Hoffman II Fixator

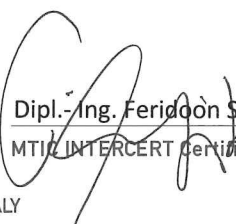
Pin to Rod Clamp, 2.0mm-8.0mm
Periarticular Pin Clamp, 2.0-8.0 mm
4-hole Coupling, 5-hole coupling, 8- hole coupling
Pin to Rod Mini Clamp, Dia. 2.0-8.0mm
Rod to Rod Mini Clamp, Dia. 2.0-8.0 mm
Post-30 Degree, Straight, Dia 4.0-11.0mm
Self-drilling Schanz Pins, Dia 2.0-6.0 mm, Length 50-450mm
Elbow Joint Mobilizer, S.S., Dia. 5.0 mm
Wrist Joint Mobilizer, S.S., Dia. 5.0 mm
Stabilization / Reduction Wrench, Thumb wheel, Hand Drill
Tube to Rod Clamp, Dia. 8.0 mm x 20.0 mm
Ankle Joint Mobilizer, Dia. 8.0-11.0 mm
Knee Joint Mobilizer, S.S., Dia. 8.0mm-11.0mm
Semi-Circular Curved Connecting Rod, S.S.
JESS fixators
Compression/Distracton tube

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6. Metallic & Carbon fiber

✓ Ilizarov Ring Fixator	Half Ring, 80-300mm Full Ring, 80-300mm 5/8 Ring, 80-300mm Italian Femoral Arch-90 Degree & 120 Degree, 100-300mm Rings with 3 Ears, 6 Ears 2/3 Ring, 80-300mm Foot Ring Telescopic Rod-Graduated, Non Graduated Threaded Rod Threaded Rod slotted Post- Male, Female Hinge- Male, Female, 90 Degree, Universal Bushing, S.S. Short Connection Plates, 2 Hole-10 Hole Connection Plates with Threaded Ends, 5 holes - 11 holes Twisted Plate, 2-4 holes Threaded Socket, 20-80mm Curved Plate, 2-14 holes Ilizarov Wire Bayonet Point, S.S., 1.5 mm Olive Wire Bayonet Point, S.S., 1.5 mm Wire Buckle, S.S. Single Pin Fixation Bolt, S.S. Wire Fixation Bolt Cannulated, S.S. Wire Fixation Bolt Slotted, S.S. Connection Bolt, 16-30mm Multiple Pin Fixation Clamp Wrenchoqube, 1-4 Holes Square Nut, S.S. Nut, S.S., 10 mm Repopix Device, S.S. Oblique Support, S.S. Washer Hanger, S.S. Flat Sided Washer, S.S. Slotted Washer, S.S. Spacing Washer, S.S. Dynamometer Tensioner, S.S.
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6. Metallic & Carbon fiber

✓ Ilizarov Ring Fixator

Manual Tensioner, S.S.
Reduction Rod Assembly, S.S.
Hinge Connecting Bolt, S.S.
Angular Diagonal Tie, S.S.
Angular Tubes, S.S.
Spring, S.S.
Adjusting Nut, S.S.
Single Joint, S.S.
Pin to Ring Clamp, Dia 1.5-4.5mm
Pin to Post Clamp, Dia 2.0-5.0mm
Rod to Ring Bolt, S.S.
L Connecting Plate, 4Holes-14 Holes
Inner Threaded Connecting Rod, 80-200mm
Bohler's Steinman Pin Holder, Small, Medium, Large
Charnley Compression Clamp with 2 pins, S.S.
Pin to Post Clamp, Dia 2.0-5.0mm
Link Joint, Small, Medium, Large
Straight Rod, 4 inches to 10 inches
L rod- Small, Medium, Large
Z Rod- Small, Medium, Large
K Wire Set - Small, Medium, Large
Open Clamp - Small, Medium, Large
Distractor- Small, Medium, Large
Hybrid Fixators For Tibia and Femur, Small, Medium, Large
Ilizarov Set- Small, Medium, Large

✓ Round Clamp Fixators

Single Rod to Double Pin Clamp, Dia 2.0mm-8.0mm
Rod to Rod, Dia. 2.0-8.0 mm
Double rod to Double Pin Clamp, Dia 2.0mm-8.0mm
Double rod to Double Rod Clamp, Dia 2.0mm-8.0mm
Connecting Rod / Tubular Rod, Dia 4.0-11mm, Length 60-600mm
Compression/Distractor Rod
Curved Connecting Rod
Elbow Joint Mobilizer, S.S., Dia. 5.0 mm-8.0mm
Wrist Joint Mobilizer, S.S., Dia. 5.0 mm-8.0mm
Stabilization / Reduction Wrench, Thumb wheel, Hand Drill
Tube to Rod Clamp, Dia. 8.0 mm x 20.0 mm
Ankle Joint Mobilizer, Dia. 8.0-11.0 mm
Knee Joint Mobilizer, S.S., Dia. 8.0mm-11.0mm
Semi-Circular Curved Connecting Rod, S.S.

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