



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

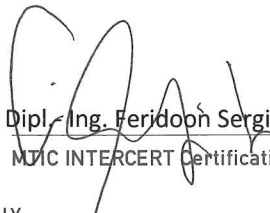
FIRST ISSUE: 28/12/2020

CURRENT ISSUE: 28/12/2020

REVISION Nr.: 00

EXPIRING DATE: 27/05/2024

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


Dipl.-Ing. Feridoon Sergizzarea
MTIC INTERCERT Certification Body



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

1. Metallic Bone Plates

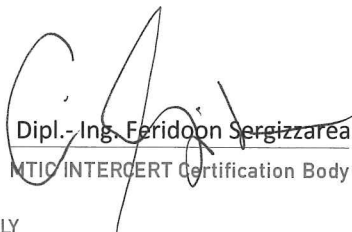
| | |
|--|-------------------|
| ✓ Locking & Non-locking DHS Plate (Long & Short Barrel), 4.5 mm- 125°, 130°, 135°, 140°, 145°, 150° | 2 Holes- 20 Holes |
| ✓ Locking & Non Locking Variable Angle DHS Plate | 2 Holes- 20 Holes |
| ✓ Locking & Non locking Double Angle DHS Plate | 2 Holes- 20 Holes |
| ✓ 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 |

FIRST ISSUE OF
THE CERTIFICATE: 28/12/2020

CURRENT ISSUE OF
THE CERTIFICATE: 28/12/2020

CERTIFICATE IN
REVISION Nr.: 00

EXPIRING DATE OF
THE CERTIFICATE: 27/05/2024


Dipl.-Ing. Feridoun Sergizare
MTIC INTERCERT Certification Body



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

1. Metallic Bone Plates

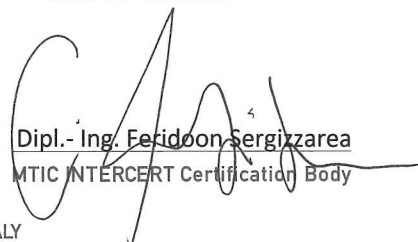
| | |
|---|-------------------|
| ✓ Limited Contact Dynamic Compression Plate, 4.5 mm- Broad | 2 Holes- 22 Holes |
| ✓ Locking & Non-locking Reconstruction Plate, Straight & Curved- 2.7 mm, 3.5 mm, 4.5 mm | 2 Holes- 22 Holes |
| ✓ Locking & Non-locking One Third Tubular Plate with collar | 2 Holes- 14 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 |

FIRST ISSUE OF
THE CERTIFICATE: 28/12/2020

CURRENT ISSUE OF
THE CERTIFICATE: 28/12/2020

CERTIFICATE IN
REVISION Nr.: 00

EXPIRING DATE OF
THE CERTIFICATE: 27/05/2024


Dipl.-Ing. Feridoon Sergizzearea
MTIC INTERCERT Certification Body



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

1. Metallic Bone Plates

| | |
|---|-----------------------|
| ✓ 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 mm | 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 | --- |

FIRST ISSUE OF
THE CERTIFICATE: 28/12/2020

CURRENT ISSUE OF
THE CERTIFICATE: 28/12/2020

CERTIFICATE IN
REVISION Nr.: 00

EXPIRING DATE OF
THE CERTIFICATE: 27/05/2024


Dipl.- Ing. Ferdinando Sergizzarea
MTIC INTERCERT Certification Body



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

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 |

FIRST ISSUE OF
THE CERTIFICATE: 28/12/2020

CURRENT ISSUE OF
THE CERTIFICATE: 28/12/2020

CERTIFICATE IN
REVISION Nr.: 00

EXPIRING DATE OF
THE CERTIFICATE: 27/05/2024

Dipl.- Ing. Feridoon Sergizzarea
MTIC/INTERCERT Certification Body



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

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 |

FIRST ISSUE OF
THE CERTIFICATE: 28/12/2020

CURRENT ISSUE OF
THE CERTIFICATE: 28/12/2020

CERTIFICATE IN
REVISION Nr.: 00

EXPIRING DATE OF
THE CERTIFICATE: 27/05/2024


Dipl.-Ing. Feridoun Sergizare
MTIC INTERCERT Certification Body



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

3. Metallic Nailing System

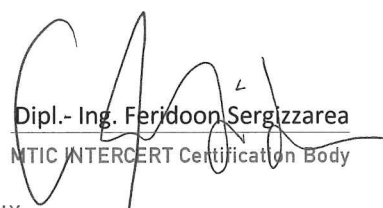
| | |
|---|----------------------|
| ✓ End Cap for Tibial & Femoral Nail | --- |
| ✓ End Cap for IMSC Nail | --- |
| ✓ End Cap for Reconstruction Nail | --- |
| ✓ End Cap for PFN Nail | --- |
| ✓ End Cap for Multiangle Tibia/Femur Nail | --- |
| ✓ End Cap for Gamma | --- |
| ✓ End Cap for PHN3 Nail | --- |
| ✓ 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 | --- |

FIRST ISSUE OF
THE CERTIFICATE: 28/12/2020

CURRENT ISSUE OF
THE CERTIFICATE: 28/12/2020

CERTIFICATE IN
REVISION Nr.: 00

EXPIRING DATE OF
THE CERTIFICATE: 27/05/2024


Dipl.- Ing. Feridoon Sergizzarea
MTIC INTERCERT Certification Body



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

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 |

FIRST ISSUE OF
THE CERTIFICATE: 28/12/2020

CURRENT ISSUE OF
THE CERTIFICATE: 28/12/2020

CERTIFICATE IN
REVISION Nr.: 00

EXPIRING DATE OF
THE CERTIFICATE: 27/05/2024


Dipl.- Ing. Feridoon Sergizzarea
MTIC INTERCERT Certification Body



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

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 |

FIRST ISSUE OF
THE CERTIFICATE: 28/12/2020

CURRENT ISSUE OF
THE CERTIFICATE: 28/12/2020

CERTIFICATE IN
REVISION Nr.: 00

EXPIRING DATE OF
THE CERTIFICATE: 27/05/2024


Dipl.-Ing. Feridoon Sergizzarea
MTIC INTERCERT Certification Body



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

✓ 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

FIRST ISSUE OF
THE CERTIFICATE: 28/12/2020

CURRENT ISSUE OF
THE CERTIFICATE: 28/12/2020

CERTIFICATE IN
REVISION Nr.: 00

EXPIRING DATE OF
THE CERTIFICATE: 27/05/2024


Dipl.-Ing. Feridoon Sergizzarea
MTIC INTERCERT Certification Body



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
 - Pertrochantric 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

FIRST ISSUE OF
THE CERTIFICATE: 28/12/2020

CURRENT ISSUE OF
THE CERTIFICATE: 28/12/2020

CERTIFICATE IN
REVISION Nr.: 00

EXPIRING DATE OF
THE CERTIFICATE: 27/05/2024

Dipl.- Ing. Feridoon Sergizzeza
MTIC INTERCERT Certification Body



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

✓ 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/Distractor tube

FIRST ISSUE OF
THE CERTIFICATE: 28/12/2020

CURRENT ISSUE OF
THE CERTIFICATE: 28/12/2020

CERTIFICATE IN
REVISION Nr.: 00

EXPIRING DATE OF
THE CERTIFICATE: 27/05/2024


Dipl.-Ing. Feridoun Sergizzarea
MTIC INTERCERT Certification Body



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

✓ 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
Repofix 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.

FIRST ISSUE OF
THE CERTIFICATE: 28/12/2020

CURRENT ISSUE OF
THE CERTIFICATE: 28/12/2020

CERTIFICATE IN
REVISION Nr.: 00

EXPIRING DATE OF
THE CERTIFICATE: 27/05/2024


Dipl.-Ing. Peridoo Sergizzarea
MTIC INTERCERT Certification Body



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

✓ 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.

FIRST ISSUE OF
THE CERTIFICATE: 28/12/2020

CURRENT ISSUE OF
THE CERTIFICATE: 28/12/2020

CERTIFICATE IN
REVISION Nr.: 00

EXPIRING DATE OF
THE CERTIFICATE: 27/05/2024


Dipl.-Ing. Feridoun Sergizzarea
MTIC INTERCERT Certification Body