

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC, as amended by 2007/47/EC on medical devices.

Manufacturer and Facility

HARDIK INTERNATIONAL

Plot No. G-2041-42/A, Kishan Gate, Lodhika G.I.D.C
Kalawad Road, Metoda-360021, Rajkot, (INDIA)

Products(s)

Orthopedic Implants

Product type(s)

See Annex 1

Trade Mark

HARDIK

Classification of medical device

Medical Devices- Class IIb

Scope of quality system

Quality of design, production, storage and distribution
Of Orthopedic Implants

Certificate number

QSA-1604837

Date of issue

12-04-2016

Date of the end of validity

11-04-2019



We have audited the quality system in accordance with the Directive 93/42/EEC, as amended by 2007/47/EC annex II (3) and found that the quality system meet the requirements of the Directive 93/42/EEC, as amended by 2007/47/EC Annex II

(Further description of the products covered by this certificate are given in the annexure attached)



Quality System Assessment
International Limited
27, Old Gloucester Street,
London, WC1N3AX, ENGLAND

Startford Ray

Certification Manager



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Registered with Registrar of Companies for England and Wales through Registration Number 8829525

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Class: IIb
Type: ORTHOPEDIC BONE SCREWS

Item Name	Size	Length
Washer	7 mm to 18 mm	-----
Cortex Screw	1.0 mm to 4.5 mm	04 mm to 100 mm
Cancellous Screw	3.5 mm to 7.0 mm	10 mm to 150 mm
LCDCP Shaft Screw	3.5 mm & 4.5 mm	10 mm to 100 mm
Locking Compression Screw	1.5 mm to 5.0 mm	10 mm to 150 mm
Locking Cancellous Screw	2.4 mm to 7.0 mm	10 mm to 160 mm
Locking Cannulated Screw	2.4 mm to 7.0 mm	10 mm to 160 mm
Malleolar Screw	3.5 mm & 4.5 mm	10 mm to 120 mm
DHS/DCS Lag Screw	-----	50 mm to 150 mm
Compression Screw	-----	20 mm to 40 mm
Cannulated Screw	3.5 mm to 7.3 mm	10 mm to 160 mm
Cannulated Interference Screw (ACL Screw)	5.0 mm to 12 mm	20 mm to 50 mm
Cannulated Herbert Screw	2.5 mm to 4.5 mm	12 mm to 50 mm
Endo Buttons	-----	-----
Suture Disc	-----	-----
Interlocking Bolt	2.4 mm to 5.0 mm	12 mm to 100 mm
Hip Locking Bolt Cannulated	5.0 mm to 7.0 mm	50 mm to 160 mm
Proximal Femoral Neck Screw	6.0 mm to 10 mm	50 mm to 160 mm
Cervical Bone Screw	3.5 mm & 4.0 mm	12 mm to 50 mm
Cervical Locking Screw	-----	-----
Cortex Screw (Self Tapping)	2.7 mm to 4.5 mm	8 mm to 100 mm
Schanz Screw	1.5 mm to 7.0 mm	100 mm to 300 mm
Customise Screw	-----	-----

Type: ORTHOPEDIC PINS, WIRES & STAPLES

Item Name	Size	Length
Stainless Steel Wire Spool	-----	14 swg to 32 swg
Cerelage Wire with Eye	0.8 mm to 2.0 mm	150 mm to 600 mm
Kirschner Wire (K Wire) With Double Trocar Tip	0.8 mm to 3.5 mm	100 mm to 300 mm
Kirschner Wire (K Wire) With Single Side Trocar Tip	0.8 mm to 3.5 mm	100 mm to 300 mm



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Kirschner Wire Threaded (K Wire)	0.8 mm to 3.5 mm	100 mm to 300 mm
Lamrinudi Wire	0.8 mm to 3.5 mm	100 mm to 300 mm
Austin Moore Pin 3 mm with 2 nuts	-----	30 mm to 200 mm
Knowles Pins 4 mm	-----	30 mm to 200 mm
Coventry Staples	Small, Medium, Large	-----
U-Staples	1.5 mm to 3.0 mm	10 mm to 40 mm
Steinman Pin	2.0 mm to 6.0 mm	100 mm to 300 mm
Steinman Pin (Central Threaded)	2.0 mm to 6.0 mm	100 mm to 300 mm
Customise Pin	-----	-----
Customise Wires	-----	-----
Customise Staples	-----	-----

Type: Orthopedic Bone Plates

Item Name	Size	Length/Holes
Mandible Plate with Centre Space	1.5 mm to 2.7 mm	2 hole to 20 hole
Mandible Plate	1.5 mm to 2.7 mm	2 hole to 20 hole
Orbital Plate with Centre Space	1.5 mm to 2.7 mm	2 hole to 20 hole
Orbital Plate	1.5 mm to 2.7 mm	2 hole to 20 hole
L Plate Angle 2 hole	1.5 mm to 2.7 mm	2 hole to 10 hole
L Plate Angle 3 hole	1.5 mm to 2.7 mm	2 hole to 10 hole
T Plate Head 2 hole	1.5 mm to 2.7 mm	2 hole to 10 hole
X Plate	1.5 mm to 2.7 mm	2 hole to 10 hole
Y Plate	1.5 mm to 2.7 mm	2 hole to 10 hole
Double End Y Plate	1.5 mm to 2.7 mm	2 hole to 10 hole
Z Plate	1.5 mm to 2.7 mm	2 hole to 10 hole
Reconstruction Plate (Round Hole)	1.5 mm to 4.5 mm	2 hole to 30 hole
Reconstruction Plate Angled (Round Hole)	1.5 mm to 4.5 mm	2 hole to 30 hole
Reconstruction Plate Mandible Shape (Round Hole)	1.5 mm to 2.7 mm	12 hole to 50 hole
DCP	2.7 mm to 4.5 mm (Small, Narrow & Broad)	2 hole to 30 hole
Quarter Tubular Plate	2.7 mm	2 hole to 20 hole
One Third Tubular Plate	2.7 mm & 3.5 mm	2 hole to 30 hole
LC-DCP	2.7 mm to 4.5 mm (Small, Narrow & Broad)	2 hole to 30 hole
Small T Ellis Plate	2.7 mm & 3.5 mm	2 hole to 14 hole
Small T Plate Right Angled	2.7 mm & 3.5 mm	2 hole to 14 hole



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Small T Plate Oblique Angled	2.7 mm & 3.5 mm	2 hole to 14 hole
Small T Plate Right Angled Head 4 Hole	2.7 mm & 3.5 mm	2 hole to 14 hole
Reconstruction Plate (DC Hole)	2.7 mm to 4.5 mm	2 hole to 30 hole
Hook Plate	3.5 mm & 4.5 mm	2 hole to 30 hole
Cloverleaf Plate	3.5 mm & 4.5 mm	2 hole to 20 hole
Calcaneal Plate	3.5 mm & 4.5 mm	50 mm to 100 mm
Locking Compression Plate	2.7 mm to 5.0 mm (Small, Narrow & Broad)	2 hole to 30 hole
Locking Compression T Plate Right Angled	2.7 mm to 5.0 mm	2 hole to 20 hole
Locking Compression T Plate Oblique Angled	2.7 mm to 5.0 mm	2 hole to 20 hole
Locking Proximal Humeral Plate	2.7 mm to 5.0 mm	2 hole to 30 hole
Locking Medial Distal Tibia Plate	2.7 mm to 5.0 mm	2 hole to 30 hole
Locking Cloverleaf Plate	2.7 mm to 5.0 mm	2 hole to 30 hole
Locking long Head Proximal Humeral Plate	2.7 mm to 5.0 mm	2 hole to 30 hole
Locking Distal Humeral Plate with Support	2.7 mm to 5.0 mm	2 hole to 30 hole
Locking Distal Humeral Plate	2.7 mm to 5.0 mm	2 hole to 30 hole
Locking Medial Distal Humeral Plate	2.7 mm to 5.0 mm	2 hole to 30 hole
Locking Superior Anterior Clavicle Plate	2.7 mm to 5.0 mm	2 hole to 30 hole
Locking Superior Anterior Clavicle Plate with Lateral Extension	2.7 mm to 5.0 mm	2 hole to 30 hole
Locking Clavicle Hook Plate	2.7 mm to 5.0 mm	2 hole to 30 hole
Semi Tubular Plate	3.5 mm & 4.5 mm	2 hole to 30 hole
T Plate	4.5 mm	2 hole to 30 hole
T Buttress Plate	4.5 mm	2 hole to 30 hole
L Plate	4.5 mm	2 hole to 30 hole
L Buttress Plate	4.5 mm	2 hole to 30 hole
Lateral Tibia head Buttress Plate	4.5 mm	2 hole to 30 hole
Condylar Buttress Plate	4.5 mm	2 hole to 30 hole
Cobra Head Plate	4.5 mm	2 hole to 30 hole
Locking Reconstruction Plate	2.7 mm to 5.0 mm	2 hole to 30 hole
Locking L Buttress Plate	3.5 mm to 5.0 mm	2 hole to 30 hole
Locking T Buttress Plate	3.5 mm to 5.0 mm	2 hole to 30 hole
Locking T Plate	3.5 mm to 5.0 mm	2 hole to 30 hole
Locking Lateral Tibia Plate	3.5 mm to 5.0 mm	2 hole to 30 hole



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Locking Proximal Tibia Plate	3.5 mm to 5.0 mm	2 hole to 30 hole
Locking Distal Femoral Plate	3.5 mm to 5.0 mm	2 hole to 30 hole
Locking Condylar Buttress Plate	3.5 mm to 5.0 mm	2 hole to 30 hole
Locking Proximal Femoral Plate	4.5 mm / 5.0 mm	2 hole to 30 hole
Locking Medical Distal Tibia Plate without Tab	2.7 mm to 5.0 mm	2 hole to 30 hole
Locking Metaphyseal Plate	3.5 mm / 4.5 mm / 5.0 mm	2 hole to 30 hole
DHS Plate (DC Hole)	120° to 150°	2 hole to 30 hole
95° DCS Plate (DC Hole)	-----	2 hole to 30 hole
DHS Plate (Round Hole)	120° to 150°	2 hole to 30 hole
95° DCS Plate (Round Hole)	-----	2 hole to 30 hole
Locking DHS Plate	120° to 150°	2 hole to 30 hole
Locking 95° DCS Plate	-----	2 hole to 30 hole
95° Condylar Plate	50 mm to 90 mm	2 hole to 30 hole
130° Condylar Plate	50 mm to 90 mm	2 hole to 30 hole
Reconstruction Plate Curved	2.7 mm to 4.5 mm	4 hole to 30 hole
Locking Calcaneal Plate	3.5 mm	40 mm to 100 mm
Locking One Third Tubular Plate	3.5 mm	2 hole to 20 hole
Locking Distal Radius Plate	2.4 mm to 3.5 mm	2 hole to 15 hole
Locking XVA-Distal Radius Plate	2.4 mm to 3.5 mm	2 hole to 15 hole
Locking Hook Plate	2.4 mm to 3.5 mm	2 hole to 15 hole
Locking Distal Fibula Plate	2.4 mm to 3.5 mm	2 hole to 20 hole
Trochanter Stabilization Plate for DHS	-----	138 mm & 148 mm
Clavicle hook Plate	Hook Depth 12 mm to 25 mm	3 hole to 10 hole
Locking Anterior Ankle Plate	4.5 mm	3 hole to 10 hole
Locking Anterolateral Distal Tibia Plate	3.5 mm & 4.5 mm	4 hole to 25 hole
Locking XLP Proximal Humeral Plate	3.5 mm	2 hole to 20 hole
Locking Proximal Radius Plate	2.4 mm & 3.5 mm	2 hole to 8 hole
Customise Plate	-----	-----

Type: ORTHOPEDIC NAILS

Item Name	Size	Length
Universal Interlocking Nail Tibia	8 mm to 14 mm	260 mm to 500 mm
Universal Interlocking Nail Femoral	8 mm to 14 mm	260 mm to 540 mm
XL Interlocking Nail Tibia	8 mm to 14 mm	260 mm to 500 mm
XL Interlocking Nail Femoral	8 mm to 14 mm	260 mm to 540 mm
Reconstruction Femoral Nail	8 mm to 14 mm	260 mm to 540 mm
Supra Condylar Nail	8 mm to 14 mm	100 mm to 500 mm



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Humeral Nail	6 mm to 10 mm	100 mm to 500 mm
Proximal Femoral Nail	8 mm to 14 mm	150 mm to 300 mm
Long Proximal Femoral Nail	8 mm to 14 mm	260 mm to 540 mm
Enders Nail	2.5 mm to 4.5 mm	150 mm to 500 mm
K Nail	5 mm to 16 mm	200 mm to 600 mm
Rush Nail	1.5 mm to 8.0 mm	100 mm to 500 mm
Square Nail	1.5 mm to 5.0 mm	100 mm to 500 mm
Elastic Nail	1.5 mm to 5.0 mm	100 mm to 500 mm
Expert Tibia Interlocking Nail	8 mm to 14 mm	260 mm to 500 mm
Expert Femoral Interlocking Nail	8 mm to 14 mm	260 mm to 540 mm
Antigrade Femoral Nail (AFN)	8 mm to 14 mm	240 mm to 440 mm
Multifunctional Femoral Nail	8 mm to 14 mm	240 mm to 440 mm
Customise Nail	-----	-----

Type: Orthopedic Spine Implants

Item Name	Size	Length
Monoaxial Screw	3.5 mm to 8.0 mm	20 mm to 70 mm
Polyaxial Screw	3.5 mm to 8.0 mm	20 mm to 70 mm
Connecting Rod	3.0 mm to 6.0 mm	30 mm to 400 mm
Connecting Block	-----	-----
Reduction Screw	3.5 mm to 8.0 mm	20 mm to 70 mm
Threaded Screw	-----	-----
Pedicle hook	-----	-----
Laminar Wide Blade Hook	-----	-----
Laminar Reduce Distance Hook	-----	-----
Laminar Angle Blade Hook	-----	-----
Inner Nut	-----	-----
Cervical Plate	-----	15 mm to 100 mm
Spinal Eco Cage	10 mm to 20 mm	5 mm to 100 mm
Expendable Cage	10 mm to 20 mm	-----
Tlif Cage (Kindney Cage)	4°,8° & 11°	4 mm to 20 mm
Plif Cage	20 mm & 25 mm	4 mm to 20 mm
Steffee Plate	-----	1 Hole to 8 Hole
Steffee Screw	4.5 mm to 6.5 mm	20 mm to 70 mm
Spine H Plate	-----	5 hole to 20 hole
Customise Spine Implants	-----	-----



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