## Government of India Directorate General of Health Services Central Drugs Standard Control Organisation Ministry of Health and Family welfare (Medical Device and Diagnostic Division) Market Standing Certificate

Certificate Number : MSC/MD/2024/000915

Dated : 24/09/2024

This is to certify that M/s. Splint Meditec Private Limited situated at address Plot No 1/2,2,3 Survey No 605, JD Industrial Area-1, At Ravki Road ,Rajkot Gujarat ,360035,9099969869, India Rajkot Gujarat 360035 9099969869 India is holding Manufacturing/Import License no. MFG/MD/2024/000617 issued on 29-AUG-2024 Under this license, the said firm is permitted to manufacture/import of medical devices as stated in manufacturing/import license.

Name of the products with their product name and dimensions if any mentioned below :

S.NO	Medical Device Details



	1. Generic Name :BONE PLATE
1	2. Brand Name :SPLINT
	3. Notified Category :Orthopaedic Implants
	4. Class of Medical Device :Class C
	5. Shelf life :NIL
	6. Sterile/Non-Sterile:Non-Sterilized
	<b>7. Intended Use</b> :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.
	8. Material of Construction: Stainless Steel 316L, Titanium
	9. Dimension: Various Dimensions
	<b>10. Model/Catalogue No./Name</b> : Straight Plate 2.0mm - Size (2 Hole to 8Hole), Micro T
	Plate 2.0mm - Size (2 Hole) - ,,Micro L Plate 2.0mm - Size (2 Hole) - ,Micro Reconstruction Plate 2.0mm - Size (4 Hole to 12 Hole) - LCP Micro Straight Plate 2.0mm - Size (4 Hole to 8
	Hole), LCP Micro Reconstruction Plate 2.0mm - Size (4 Hole to 12 Hole) - ,, LCP Micro
	Condylar Plate 2.0mm - Size (2 Hole to 10 Hole) - ,,LCP Micro Rotation Correction Plate 2.0
	mm - Size (2 Hole to 10 Hole) - ,,LCP Micro Y Plate 2.0mm - Size (2 Hole to 10 Hole) - ,,LCP
	Micro T Plate (Short Head) 2.0mm - Size (2 Hole to 10 Hole) - LCP Micro T Plate (Long Head)
	2.0mm - Size (2 Hole to 10 Hole), Dynamic Compression plate 2.7mm - Size (2 Hole to 10
	Hole) - ,,Quarter Tubular Plate 2.7mm - Size (2 Hole to 10 Hole) - ,,Reconstruction Plate 2.7
	mm - Size (2 Hole to 24 Hole) - "Micro T Plate 2.7mm - Size (3 Hole) - "Micro L Plate 2.7mm
	- Size (3 Hole) - ,,LCP Cloverleaf Fusion Plate 2.7mm - Size (Small - ,,Large) - ,,LCP First MTP
	Fusion Plate 2.7mm (Left & Right) - Size (Small - ,,Large) - ,,LCP First TMT Fusion Plate 2.7
	mm - Size (Small Large) - LCP Second TMT Fusion Plate 2.7mm - Size (Small,Large) - ,,LCP T
	Fusion Plate 2.7mm - Size (Small - ,,Large) - ,,LCP L Fusion Plate 2.7mm (Left & Right) - Size
	(Small - ,,Large) - ,,LCP X Fusion Plate 2.7mm - Size (Extra Small - ,,Small - ,,Medium - ,,
	Large) - ,,LCP Straight Fusion Plate 2.7mm - Size (4Hole) - ,,LCP Foot Calcaneal Plate 2.7mm
	(Left & Right) - Size (Small - ,,Large) - ,,One Third Tubular Plate 3.5mm - Size (4 Hole to 12
	Hole) - ,,Small DCP Plate 3.5mm - Size (4 Hole to 16 Hole) - Small LC-DCP Plate 3.5mm - Size
	(4 Hole to 16 Hole), Reconstruction Plate Straight (DC Hole) 3.5mm - Size (4 Hole to 24 Hole)
	- "Reconstruction Plate Thin (Round Hole) 3.5mm - Size (4 Hole to 24 Hole) - "Small T-Plate
	Right Angled 3.5mm - Size (3 Hole to 10 Hole) - ,,Small T-Plate Oblique Angled 3.5mm - Size
	(3 Hole to 10 Hole) - ,,Small T-Plate Right Angled (Head 4Hole) 3.5mm - Size (3 Hole to 10
	Hole) - ,,Clavicle S Plate 3.5mm - Size (6 hole to 9 hole) - Cloverleaf Plate 3.5mm - Size (3
	Hole to 10 Hole), Clavicle Hook Plate 3.5mm - Size (4 Hole to 8 Hole) - ,,Distal Humerus
	Plate With Support 3.5mm - Size (3 Hole to 12 Hole) - "Medial Distal Humerus Plate 3.5mm
	- Size (3 Hole to 12 Hole) - "Pelvic Reconstruction Plate Straight (Thin) 3.5mm - Size (4 Hole
	to 20 Hole) - ,,Pelvic Reconstruction Plate Curved (Thin) 3.5mm - Size (4 Hole to 16 Hole) - ,
	Pelvic Reconstruction Plate Angled (Thin) 3.5mm - Size (4 Hole to 16 Hole) - ,,Pelvic
	Reconstruction Plate Straight (DC Hole) 3.5mm - Size (4 Hole to 20 Hole) - Pelvic
	Reconstruction Plate Curved (DC Hole) 3.5mm - Size (4 Hole to 16 Hole), Pelvic Symphyseal
	Plate 3.5mm - Size (4 Hole to 6 Hole) - ,,Pelvic Symphyseal Plate (2 DC Hole) 3.5mm - Size (4
	Hole to 6 Hole) - ,,Pelvic Spring Plate 3.5mm - Size (1 Hole to 3 Hole) - ,,Reconstruction Y
	Plate 3.5mm - Size (4 Hole to 10 Hole) - ,,Eight Plate 3.5mm - Size (20mm - ,,25mm - ,,
	30mm) - "Semi Tubular Plate 4.5mm - Size (4 Hole to 12 Hole) - "Narrow DCP Plate 4.5mm
	- Size (5 Hole to 16 Hole) - Narrow LC-DCP Plate 4.5mm - Size (5 Hole to 16 Hole),Broad
	DCP Plate 4.5mm - Size (5 Hole to 16 Hole) - ,,Broad LC-DCP Plate 4.5mm - Size (5 Hole to
	16 Hole) - ,,Reconstruction Plate straight (DC Hole) 4.5mm - Size (5 Hole to 16 Hole) - ,,
	Reconstruction Plate straight (Thin) 4.5mm - Size (5 Hole to 16 Hole) - ,,T - Plate 4.5mm -
	Size (3 Hole to 12 Hole) - ,,T - Buttress Plate 4.5mm - Size (3 Hole to 12 Hole) - ,,L - Buttress
	Plate 4.5mm (Left & Right) - Size (3 Hole to 12 Hole) - ,,Proximal Lateral Tibia Plate 4.5/6.
	5mm - Size (5 Hole to 15 Hole) - Condylar Buttress Plate 4.5mm (Right / Left) - Size (5 Hole
	to 15 Hole),Cobra Plate 4.5mm - Size (5 Hole to 14 Hole) - ,,Distal Tibia Plate 4.5mm - Size
	(3 Hole to 13 Hole) - "Proximal Tibia Plate 4.5mm - Size (3 Hole to 13 Hole) - "Proximal
	Femoral Plate 4.5mm - Size (3 Hole to 13 Hole) - ,,Distal Femoral Plate 4.5mm - Size (3 Hole
	to 13 Hole) - "Spoon Plate 4.5mm - Size (5 Hole - "6 Hole) - "LCP One Third Tubular Plate
	(Combi- Hole) 3.5mm - Size (4 Hole to 12 Hole) - ,,Eight Plate 4.5mm - Size (12mm - ,,16mm
	- ,,20mm - ,,25mm - ,,30mm) - ,,LCP One Third Tubular Plate 3.5mm - Size (4 Hole to 12
	Hole) - LCP Small Compression Plate 3.5mm - Size (4 Hole to 16 Hole), LCP Reconstruction
	Plate 3.5mm - Size (4 Hole to 16 Hole) - ,,LCP Reconstruction Plate (Thin) 3.5mm - Size (4
	Hole to 16 Hole) - ,,LCP T Plate Right Angled 3.5mm - Size (3 Hole to 10 Hole) - ,,LCP T Plate
	Oblique Angled 3.5mm (Left & Right) - Size (3 Hole to 10 Hole) - ,,LCP Superior Anterior
	Clavicle Plate 3.5mm (Left & Right) - Size (6 hole to 9 hole) - ,,LCP Superior Anterior Clavicle
	Plate With Lateral Extension 3.5mm (Left & Right) - Size (3 hole to 9 hole) - LCP Clavicle
	Hook Plate 3.5mm Hook Depth 12mm (Left & Right) - Size (4 Hole to 8 Hole), LCP Clavicle
	Hook Plate 3.5mm Hook Depth 15mm (Left & Right) - Size (4 Hole to 8 Hole) - ,,LCP Clavicle
	Hook Plate 3.5mm Hook Depth 18mm (Left & Right) - Size (4 Hole to 8 Hole) - ,,LCP

Proximal Humerus Plate (Long Head Philos) 3.5mm - Size (2 Hole to 14 Hole) - ,,LCP Peri-Articular Proximal Humerus Plate 3.5mm (Left & Right) - Size (2 Hole to 12 Hole) - ,,LCP Distal Humerus Plate 3.5mm (Left & Right) - Size (3 Hole to 12 Hole) - ,,LCP Distal Humerus Plate With Support 3.5mm (Left & Right) - Size (3 Hole to 12 Hole) - LCP Medial Distal Humerus Plate 3.5mm (Left & Right) - Size (3 Hole to 12 Hole), LCP Metaphyseal Distal Humerus Plate 3.5mm - Size (5 Hole to 15 Hole) - "LCP Extra-Articular Distal Humerus Plate 3.5mm (Left & Right) - Size (4 Hole to 14 Hole) - ,,LCP Proximal Tibia Plate 3.5mm (Left & Right) - Size (5 Hole to 14 Hole) - ,,LCP Anatomical Proximal Tibia Plate (Raft) 3.5mm - Size (5 Hole to 15 Hole) - ,,LCP Proximal Medial Tibia Plate 3.5mm - Size (4 Hole to 14 Hole) - ,, LCP Posterior Medial Proximal Tibia Plate 3.5mm - Size (3 Hole to 12 Hole) - ,,LCP Anterolateral Distal Tibia Plate 3.5mm (Left & Right) - Size (5 Hole to 15 Hole) - LCP Medial Distal Tibia Plate With Tab 3.5mm (Left & Right) - Size (4 Hole to 14 Hole), LCP Medial Dista Tibia Plate (Low Band) 3.5mm (Left & Right) - Size (4 Hole to 14 Hole) - ,,LCP Olecranon Plate 3.5mm (Left & Right) - Size (4 Hole to 12 Hole) - ,,LCP Distal Febula Plate 3.5mm - Size (3 Hole to 10 Hole) - ,,LCP Distal Febula Plate 2.7/3.5mm (Left & Right) - Size (3 Hole to 10 Hole) - ,,LCP Proximal Radius Neck Plate 2.4/2.7mm - Size (2 Hole to 4 Hole) - ,,LCP Proximal Radius Rim Plate 2.4/2.7mm (Left & Right) - Size (2 Hole to 4 Hole) - LCP Calcaneal Plate 3.5mm (Left & Right) - Size (64mm,69mm - ,,76mm - ,,81mm) - ,,LCP VA Distal Febula Plate with Support 2.7/3.5mm (Left & Right) - Size (4 Hole to 10 Hole) - ,,LCP Hook Plate 3.5 mm - Size (3 Hole to 10 Hole) - ,,LCP Volar Distal Radius Plate - ,,Column 2.4/2.7mm (Left 8 Right) - Size (3 Hole to 6 Hole) - ,,LCP Volar Distal Radius Plate 2.4/2.7mm (Left & Right) -Size (3 Hole to 6 Hole) - ,,LCP Duraline Distal Kopis Plate 2.7/3.5mm (Left & Right) - Size (2 Hole to 6 Hole) - "LCP Distal Radius Plate - "Juxta articular 2.4/2.7mm (Left & Right) - Size (3 Hole to 6 Hole) - ,,LCP Distal Radius Buttress Plate 2.4/2.7mm (Left & Right) - Size (3 Hole to 5 Hole) - LCP Distal Radius Plate, Extra articular (Head 4 Hole) 2.4/2.7mm (Left & Right) -Size (3 Hole to 5 Hole) - , LCP Distal Radius Plate - , Extra articular (Head 5 Hole) 2.4/2.7mn (Left & Right) - Size (3 Hole to 5 Hole) - ,,LCP Distal Radius Plate - ,,Straight 2.4/2.7mm - Size (3 Hole to 5 Hole) - "LCP Distal Radius L Plate (Head 2 Hole) 2.4/2.7mm (Left & Right) - Size (3 Hole to 5 Hole) - "LCP Distal Radius L Plate (Head 3 Hole) 2.4/2.7mm (Left & Right) - Size (3 Hole to 5 Hole) - ,,LCP Distal Radius L Plate - ,,Oblique Angle (Head 3 Hole) 2.4/2.7mm (Left & Right) - Size (3 Hole to 5 Hole) - LCP Distal Radius T Plate 2.4/2.7mm - Size (3 Hole to 5 Hole), LCP Volar Distal Radius Plate - ,, Variable Angle (Head 6 Hole) 2.4/2.7mm (Left & Right) - Size (2 Hole to 6 Hole) - ,,LCP Volar Distal Radius Plate - ,,Variable Angle (Head 7 Hole) 2.4/2.7mm (Left & Right) - Size (2 Hole to 6 Hole) - ,,LCP Volar Distal Radius Rim Plate 2.4/2.7mm (Left & Right) - Size (2 Hole to 6 Hole) - ,,LCP Pelvic Reconstruction Plate Straight (Thin) 3.5mm - Size (4 Hole to 20 Hole) - ,,LCP Pelvic Reconstruction Plate Curved (Thin) 3.5 mm - Size (4 Hole to 16 Hole) - "LCP Pelvic Symphyseal Plate 3.5mm - Size (4 Hole to 6 Hole) - LCP Pelvic Reconstruction Plate Angled (Thin) 3.5mm - Size (4 Hole to 16 Hole), LCP Pelvic Symphyseal Plate (2 DC Hole) 3.5mm - Size (4 Hole to 6 Hole) - ,,LCP T-Plate Right Angle (Head 4 Hole) 3.5mm - Size (3 Hole to 10 Hole) - ,,LCP Pilon Plate 3.5mm - Size (7 Hole to 9 Hole) - ,,LCP Wrist Fusion Plate 3.5mm - Size (8 Hole to 9 Hole) - ,,LCP Cloverleaf Plate 3.5mm - Size (3 Hole to 6 Hole) - ,,LCP Pediatric Hip Plate 3.5mm - Size (100° - ,,110° ,,120° - ,,150°) - ,,LCP Narrow Plate 4.5/5.0mm - Size (5 Hole to 16 Hole) - ,,LCP Broad Plate 4.5/5.0mm - Size (5 Hole to 16 Hole) - ,,LCP Reconstruction Plate 4.5/5.0mm - Size (5 Hole to 16 Hole) - ,,LCP Reconstruction Plate (Thin) 5.0mm - Size (5 Hole to 16 Hole) - LCP T Plate 4.5/5.0mm - Size (3 Hole to 12 Hole), LCP T Buttress Plate 4.5/5.0mm - Size (3 Hole to 12 Hole) - ,,LCP L Buttress Plate 4.5/5.0mm (Left & Right) - Size (3 Hole to 12 Hole) - ,,LCP Proximal Lateral Tibia Plate 4.5/5.0mm (Left & Right) - Size (3 Hole to 15 Hole) - ,,LCP Proximal Femur Plate 4.5/5.0mm (Left & Right) - Size (3 Hole to 15 Hole) - ,,LCP Distal Femur Plate 4.5/5.0mm (Left & Right) - Size (3 Hole to 15 Hole) - ,,LCP Tomofix Proximal Medial Tibia Plate 4.5/5.0mm - Size (4 Hole) - , LCP Tomofix Medial Distal Femoral Plate 4.5 /5.0mm - Size (4 Hole) - ,,LCP Trochanteric Buttress Plate Combined with PFN 4.5/5.0mm X 2 Hole - Size (2 Hole) - ,,LCP Medial Distal Femoral Plate 4.5/5.0mm (Left & Right) - Size (2 Hole to 12 Hole) - LCP Proximal Femur Plate 4.5/5.0/6.0mm (Left & Right) - Size (4 Hole to 14 Hole), LCP Metaphyseal Plate 3.5/4.5/5.0mm - Size (5 Hole to 12 Hole) - , LCP Proximal Femur Plate Hook 4.5/5.0mm (Left & Right) - Size (2 Hole to 14 Hole) - ,,LCP Proximal Femur Multiaxail compression Plate 4.5/5.0mm - Size (5 Hole) - "LCP Broad Curved Plate 4.5/5.0mm - Size (12 Hole to 18 Hole) - ,,LCP Condylar Femoral Plate 4.5/5.0mm (Left & Right) - Size (3 Hole to 15 Hole) - ,,LCP Cable Plate 4.5/5.0mm - Size (6 Hole to 10 hole) -LCP Cable Plate Hook 4.5/5.0mm - Size (2 Hole to 14 hole) - ,,LCP Pediatric Hip Plate 4.5/5 0mm - Size (100° - "110° - "120° - "150°) - "LCP Tomofix Lateral Tibia Plate 4.5/5.0mm -Size (3 Hole) - LCP Tomofix Distal Femoral Plate 4.5/5.0mm - Size (4 Hole), Pediatric DHS Plate (DC Hole) 125°/ 130°/ 135°/ 140° - Size (2 Hole to 8 hole) - ,,DHS Plate (DC Hole) 38mm/32mm/25mm Barrel 125°/ 130°/ 135°/ 140°/ 145° - Size (2 Hole to 16 hole) - ,,DHS Plate (Round Hole) 38mm/32mm/25mm Barrel 125°/ 130°/ 135°/ 140°/ 145° - Size (2 Hole to 16 hole) - "LCP DHS Plate 38mm/32mm/25mm Barrel 125°/ 130°/ 135°/ 140°/ 145° -Size (2 Hole to 16 hole) - ,,DCS 95° Plate (DC Hole) - Size (4 Hole to 16 hole) - ,,LCP DCS 95° Plate - Size (4 Hole to 12 hole) - ,,Blade Plate 90°/ 95°/ 125°/ 130°/ 135°/ - Size (4 Hole to 12

	hole) - ,,Trochanter Stabilizing Plate - Size (138mm - ,,148mm) - ,,LCP Trochanter Stabilizing Plate - Size (3 Hole) - ,
2	1. Generic Name :BONE SCREW
2	2. Brand Name : SPLINT
	3. Notified Category :Orthopaedic Implants
	4. Class of Medical Device :Class C 5. Shelf life :NIL
	6. Sterile/Non-Sterile:Non-Sterilized
	7. 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.
	8. Material of Construction: Stainless Steel 316L, Titanium
	9. Dimension: Various Dimensions
	<b>10. Model/Catalogue No./Name :</b> Micro Cortex Screw (Star Head) 2.0mm - Size (6mm to
	12mm) - Micro LHS Screw (Star Head) 2.0mm - Size (6mm to 12mm),Cortex Screw (Low
	Profile Star Head) 2.7mm - Size (10mm to 30mm) - ,,LHS Screw (Low Profile Star Head) 2.7 mm - Size (10mm to 30mm) - Washer - Size (7mm,10mm - ,,13mm) - ,,Cortex Screws (self-
	tapping) 2.7mm - Size (10mm to 30mm) - ,,Cortex Screws 20 TPI (self-tapping) 3.5mm - Size
	(12mm to 60mm) - ,,Cortex Screws 14 TPI (self-tapping) 3.5mm - Size (12mm to 60mm) - ,,
	Cortex Screws (self-tapping) 4.5mm - Size (14mm to 90mm) - "Malleolar Screws 4.5mm -
	Size (25mm to 100mm) - ,,LHS Screws (self-tapping) 2.7mm - Size (10mm to 50mm) - ,,LHS
	Screws (self-tapping) 3.5mm - Size (12mm to 90mm) - LHS Screws (self-tapping) 5.0mm -
	Size (14mm to 100mm), Cancellous Screws (Short Thread) 4.0mm - Size (14mm to 80mm) -
	,,Cancellous Screws (Full Thread) 4.0mm - Size (14mm to 80mm) - ,,Cancellous Screws (16mm Thread) 6.5mm - Size (25mm to 120mm) - ,,Cancellous Screws (32mm Thread) 6.5
	mm - Size (45mm to 120mm) - ,,Cancellous Screws (Full Thread) 6.5mm - Size (25mm to
	120mm) - ,,LHS Cancellous Screws (Short Thread) 3.5mm - Size (14mm to 90mm) - ,,LHS
	Cancellous Screws (Full Thread) 3.5mm - Size (14mm to 90mm) - ,,LHS Cancellous Screws
	(16mm Thread) 5.0mm - Size (25mm to 100mm) - LHS Cancellous Screws (32mm Thread)
	5.0mm - Size (25mm to 100mm),LHS Cancellous Screws (Full Thread) 5.0mm - Size (25mm
	to 100mm) - "Cannulated Screw (Short Thread) Tapper Head 6.0mm - Size (25mm to
	120mm) - ,,LHS Cannulated Screw (Full Thread) 6.0mm - Size (25mm to 120mm) - ,,
	Cannulated Cancellous Screws (Short Thread) 4.0mm - Size (14mm to 80mm) - ,,
	Cannulated Cancellous Screws (Full Thread) 4.0mm - Size (14mm to 80mm) - ,,Cannulated Cancellous Screws (16mm Thread) 6.5mm - Size (25mm to 120mm) - ,,Cannulated
	Cancellous Screws (32mm Thread) 6.5mm - Size (45mm to 120mm) - Cannulated
	Cancellous Screws (Full Thread) 6.5mm - Size (25mm to 120mm), Cancellous Screws (16mm
	Thread) 5.0mm - Size (25mm to 100mm) - ,,Cancellous Screws (32mm Thread) 5.0mm -
	Size (25mm to 100mm) - ,,Cannulated Cancellous Screws (16mm Thread) 7.0mm - Size
	(25mm to 120mm) - ,,Cannulated Cancellous Screws (32mm Thread) 7.0mm - Size (25mm
	to 120mm) - ,,Cannulated Cancellous Screws (Full Thread) 7.0mm - Size (25mm to 120mm) - ,,LHS Screws (Star Head) 2.4mm - Size (10mm to 30mm) - ,,LHS Screws (Star Head) 2.7mr
	- Size (10mm to 50mm) - LHS Screws (Star Head) 2.7mm
	Screws (Star Head) 5.0mm - Size (14mm to 100mm) - ,,LHS Cancellous Screws (Star Head)
	3.5mm - Size (14mm to 90mm) - ,,Cancellous Screws (16mm Thread) 6.0mm - Size (25mm
	to 120mm) - ,,LHS Cancellous Screws (Star Head) 5.0mm - Size (25mm to 100mm) - ,,
	Cancellous Screws (32mm Thread) 6.0mm - Size (25mm to 120mm) - ,,Cancellous Screws
	(Full Thread) 6.0mm - Size (25mm to 120mm) - ,,Cortex Screws (Low Profile) 3.5mm - Size
	(12mm to 60mm) - ,,Cortex Screws (Low Profile) 4.5mm - Size (14mm to 80mm) - ,,Herbert Screw Cannulated 2.0mm - Size (12mm to 40mm) - Herbert Screw Cannulated 2.5mm -
	Size (12mm to 40mm), Herbert Screw Cannulated 3.5mm - Size (12mm to 60mm) - ,,
	Headless Compression Screw 2.5mm - Size (08mm to 30mm) - ,,Headless Compression
	Screw 3.5mm - Size (16mm to 50mm) - ,,Headless Compression Screw 4.0mm - Size (16mm
	to 50mm) - ,,Headless Compression Screw 4.7mm - Size (20mm to 50mm) - ,,Headless
	Compression Screw 5.5mm - Size (25mm to 60mm) - ,,Headless Compression Screw 6.5
	mm - Size (25mm to 100mm) - "Headless Compression Screw 7.5mm - Size (25mm to
	100mm) - ,,,DHS/DCS Lag Screw - Size (50mm to 120mm) - ,,Pediatric DHS Lag Screw - Size
	(50mm to 100mm) - FNS Bolt - Size (75mm to 115mm), FNS Antirotation Screw - Size
	(75mm to 115mm) - ,,Hip Screw 6.5mm - Size (20mm to 50mm) - ,,End Cap For Elastic Nail 2.5mm - Size (2.5mm - ,,4.0mm) - ,,End Cap For Humeral Nail - Size (0mm - ,,5mm - ,,
	10mm) - "End Cap For Tibia & Femoral Nail - Size (0mm) - "PFNA-2 Nail Cap - Size (0mm -
	5mm - ,,10mm) - ,,End Cap For Proximal Femoral Nail - Size (0mm) - ,,End Cap For Distal
	Femoral Nail - Size (0mm) - ,,Interlocking Screws 2.9mm - Size (18mm to 40mm) - ,,
	Interlocking Screws 3.4mm - Size (18mm to 50mm) - Interlocking Screws 3.9mm - Size
	(18mm to 50mm), Interlocking Screws 4.9mm - Size (18mm to 80mm) - ,,Lag Screw For PFN
	6.4mm - Size (50mm to 120mm) - ,,Lag Screw For PFN 8.0mm - Size (50mm to 120mm) - ,,
	PFNA-2 Blade - Size (70mm to 120mm) - ,,Lag Screw For PFNA-2 - Size (70mm to 120mm) - ,,Humerus Blade - Size (30mm to 60mm) - ,

3	1. Generic Name :INTERLOCKING INTRAMEDULLARY NAILS
Ū	2. Brand Name :SPLINT
	3. Notified Category :Orthopaedic Implants
	4. Class of Medical Device :Class C 5. Shelf life :NIL
	6. Sterile/Non-Sterile:Non-Sterilized
	<b>7. Intended Use</b> :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.
	8. Material of Construction: Stainless Steel 316L, Titanium
	9. Dimension: Various Dimensions
	10. Model/Catalogue No./Name :Elastic Nail 440mm - Size (Ø 1.5mm to Ø 4.5mm),
	Square Nail For Radius Ø 2.0mm - ,,2.5mm - ,,3.0mm - ,,3.5mm - Size (180mm to 300mm) -
	,,Square Nail For Ulna - Ø 2.0mm,2.5mm - ,,3.0mm - ,,3.5mm - Size (180mm to 300mm) - ,,
	Rush Nail Ø 2.0mm - ,,2.5mm - ,,3.0mm - ,,3.5mm - ,,4.0mm - ,,4.5mm - ,,5.0mm - Size
	(180mm to 300mm) - ,,Enders Nail 2.5mm - ,,3.5mm - ,,4.5mm - ,,- Size (180mm to 400mm)
	- "Screw Nail Ø 2.0mm - "2.5mm - "3.0mm - "3.5mm - "4.0mm - Size (120mm to 300mm) -
	"Humeral Nail Ø 6mm - "7mm - "8mm - Size (180mm to 300mm) - "Tibia Interlocking Nail
	Ø 8mm - "9mm - "10mm - "11mm - Size (280mm to 400mm) - "Tibia Interlocking Nail (Tip
	Locking) - Ø 8mm,9mm - ,,10mm - ,,11mm - Size (280mm to 400mm) - ,,Femoral Interlocking Nail Ø 9mm - ,,10mm , ,,11mm - ,,12mm - Size (320mm to 460mm) - ,,
	Proximal Femoral Nail 130° Ø 9mm - ,,10mm - ,,11mm - ,,12mm - Size (320mm to 400mm) - ,,
	- "Proximal Femoral Nail 135° Ø 9mm - "10mm - "11mm - "12mm - Size (180mm to
	460mm) - ,,PFNA-2 125°/130°/135° Ø 9mm - ,,10mm - ,,11mm - ,,12mm - Size (170mm to
	460mm) - ,,Distal Femoral Nail Ø 9mm - ,,10mm - ,,11mm - ,,12mm - Size (150mm to
	350mm) - ,,Smart Tibia Nail Ø 8mm - ,,9mm - ,,10mm - ,,11mm - Size (280mm to 400mm) -
	"Supracondylar Nail (IMSC) - Ø 9mm,10mm - "11mm - "12mm - Size (150mm to 350mm) -
	"Syrus Femoral Nail Ø 9mm - "10mm - "11mm - "12mm - Size (320mm to 460mm) - "
	Gamma Femoral Nail Ø 9mm - ,,10mm - ,,11mm - ,,12mm - Size (320mm to 460mm) - ,,
	Antegrade Femoral Nail (AFN) Ø 9mm - ,,10mm - ,,11mm - ,,12mm - Size (320mm to
	460mm) - ,,Tibia Interlocking Nail (High Bend) Ø 8mm - ,,9mm - ,,10mm - ,,11mm - Size
	(280mm to 400mm) - ,,Ankle Nail Ø 8mm - ,,9mm - ,,10mm - Size (180mm to 270mm) - ,,
	Humeral Nail with Multilock - Ø 6mm,7mm - "8mm - Size (180mm to 300mm) - "Humeral
	Nail with Blade Ø 6mm - ,,7mm - ,,8mm - ,,9mm - Size (180mm to 300mm) - ,,Universal
	Interlocking Tibia Nail Size - 8.0mm to 14mm Length, Universal Interlocking Femoral Nail
	Size - 8.0mm to 14mm Length, Unreamed Tibia Nail Size - 8.0mm to 14mm Length
	ILIH, GOVEN

4	1. Generic Name : SPINAL IMPLANT
	2. Brand Name :SPLINT
	3. Notified Category :Orthopaedic Implants
	4. Class of Medical Device :Class C
	5. Shelf life :NIL
	6. Sterile/Non-Sterile:Non-Sterilized
	7. 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.
	8. Material of Construction: Stainless Steel 316L, Titanium
	9. Dimension: Various Dimensions
	10. Model/Catalogue No./Name : PEDICAL SCREW Monoaxial Screw (Regular) - Ø 4.5mm,
	5.5mm, 6.5mm - Size (25mm to 50mm), Polyaxial Screw (Regular) Ø 4.5mm, 5.5mm, 6.5
	mm - Size (25mm to 50mm), Monoaxial Reduction Screw (Regular) - Ø 4.5mm, 5.5mm, 6.5
	mm - Size (25mm to 50mm), Polyaxial Reduction Screw (Regular) Ø 4.5mm, 5.5mm, 6.5mm
	- Size (25mm to 50mm), Monoaxial Screw (Premium) Ø 4.5mm, 5.5mm, 6.5mm - Size
	(25mm to 50mm), Polyaxial Screw (Premium) Ø 4.5mm, 5.5mm, 6.5mm - Size (25mm to
	50mm), Monoaxial Reduction Screw (Premium) Ø 4.5mm, 5.5mm, 6.5mm - Size (25mm to
	50mm), Polyaxial Reduction Screw (Premium) Ø 4.5mm, 5.5mm, 6.5mm - Size (25mm to
	50mm), Polyaxial Screw (Dual Thread) Ø 4.5mm, 5.5mm, 6.5mm - Size (25mm to 50mm),
	Monoaxial Screw (Dual Thread) - Ø 4.5mm, 5.5mm, 6.5mm - Size (25mm to 50mm),
	Monoaxial Reduction Screw (Dual Thread) Ø 4.5mm, 5.5mm, 6.5mm - Size (25mm to
	50mm), Polyaxial Reduction Screw (Dual Thread) Ø 4.5mm, 5.5mm, 6.5mm - Size (25mm to
	50mm), Connecting Rod 5.5mm - Size (50mm to 400mm), Connecting Rod (Hexagonal End)
	5.5mm - Size (50mm to 200mm), Connecting Rod 3.0mm - Size (40mm to 100mm),
	Transverse Connector, Crosslink Connector - Size (Small, Medium, Large), Spinal Hook
	Staple - Size (Small, Large), Minimal Invensive Spinal (MIS) Polyaxial Screw Ø 5.5mm, 6.5
	mm, 7.5mm - Size (30mm to 50mm), Pre Bend Connecting Rod (MIS) 5.5mm - Size (35mm
	to 150mm) - CAGE / SPACERTLIF (Transformational Lumbar Interbody Fusion) Bullet Cage
	25mm, 30mm - Size (7mm to 12mm), TLIF (Transformational Lumbar Interbody Fusion)
	Kidney Cage 04°, 08°, 11° - Size (7mm to 12mm), PLIF (Posterior Lumbar Interbody Fusion)
	Cage 20mm, 25mm - Size (7mm to 12mm), Mesh Cage Ø 10mm, 12mm, 14mm, 16mm,
	18mm, 20mm - Size (50mm, 100mm), Expandable Cage Ø 12mm, 14mm, 16mm, 18mm,
	20mm - Size (20mm to 75mm), CERVICLE PLATE & SCREW Cervical Plate - Size (22mm to
	60mm), Cervical Bone Screw - Size (10mm to 18mm), Cervical Revision Bone Screw - Size
	(10mm to 18mm), Self-Drilling Cervical Bone Screw - Size (10mm to 18mm) - Anterior
	Cervical Interbody Fusion Cage 12mm, 14mm, 16mm - Size (4mm to 7mm), Cervical
	Impacted Fusion Cage 14mm, 16mm - Size (mm to 8mm), Posterior Multiaxial Cancellous
	Screw (Lateral Mass) 3.5mm, 4.0mm - Size (14mm to 32mm), Connecting Rod (PMCS) Ø 3.2
	mm - Size (25mm to 200mm), Posterior Hook Ø 3.2mm - Size (4.5mm, 6.0mm), Posterior
	Connector 3.2mm, 5.0mm - Size (9mm to 15mm), Posterior Occipital T Plate - Size (32mm
	to 44mm), Posterior Occipital Y Plate (With Connector Set) - Size (32mm to 44mm) -
	Posterior Occipital Cancellous Screw - Size (12mm), Posterior Occipital Connecting Rod
	(Bend) 3.2mm - Size (65mm to 85mm), Posterior Occipital Combi. Connecting Rod (Step
	Rod) 3.2 mm (150 mm) x 5.5 mm (270 mm) - Size (), Posterior Occipital Plate with Rod 3.2
	mm x 250 mm - Size (4 Hole)
1	

5	1. Generic Name :BONE PINS AND WIRES
5	2. Brand Name :SPLINT
	3. Notified Category :Orthopaedic Implants
	4. Class of Medical Device : Class C
	5. Shelf life :NIL
	6. Sterile/Non-Sterile:Non-Sterilized
	7. 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.
	8. Material of Construction: Stainless Steel 316L, Titanium
	9. Dimension: Various Dimensions
	<b>10. Model/Catalogue No./Name :</b> Wire Spool - Size (16 swg to 26 swg) - Cerclage Wire
	With Eye - Size (0.8mm to 1.5mm), Kirschner wires (K-wire) 150mm - Size (0.8mm to 3.5
	mm) - "Kirschner wires (K-wire) 225mm - Size (0.8mm to 3.5mm) - "Kirschner wires (K-
	wire) 300mm - Size (0.8mm to 3.5mm) - Kirschner wires (K-wire) 150mm (Sterile) - Size (0.8
	mm to 3.5mm), Kirschner wires (K-wire) 225mm (Sterile) - Size (0.8mm to 3.5mm) - ,,
	Kirschner wires (K-wire) 300mm (Sterile) - Size (0.8mm to 3.5mm) - ,,Kirschner wires (K-
	wire) Single Side Treaded 150mm - Size (0.8mm to 3.5mm) - "Kirschner wires (K-wire)
	Single Side Treaded 225mm - Size (0.8mm to 3.5mm) - ,,Kirschner wires (K-wire) Single Side
	Treaded 300mm - Size (0.8mm to 3.5mm) - ,,Kirschner wires (K-wire) Double Side Treaded
	150mm - Size (0.8mm to 3.5mm) - ,,Kirschner wires (K-wire) Single Side Treaded 225mm -
	Size (0.8mm to 3.5mm) - Kirschner wires (K-wire) Double Side Treaded 300mm - Size (0.8
	mm to 3.5mm), Steinman Pin 2.5mm - Size (100mm to 250mm) - ,,Steinman Pin 3.0mm -
	Size (100mm to 250mm) - ,,Steinman Pin 3.5mm - Size (100mm to 250mm) - ,,Steinman Pin
	4.0mm - Size (100mm to 250mm) - ,,Steinman Pin 4.5mm - Size (100mm to 250mm) - ,,
	Steinman Pin 5.0mm - Size (100mm to 250mm) - ,,Steinman Pin 5.5mm - Size (100mm to
	250mm) - "Steinman Pin 6.0mm - Size (100mm to 250mm) - "Steinman Pin (Central
	Threaded) Ø 3.5/4.0mm - ,,Ø 4.5/5.0mm - Size (225mm) - ,,Schanz Screw (16mm Thread) Ø
	2.0mm - Size (100mm to 250mm) - Schanz Screw (16mm Thread) Ø 2.5mm - Size (100mm
	to 250mm), Schanz Screw (16mm Thread) Ø 3.5mm - Size (100mm to 250mm) - ,,Schanz
	Screw (16mm Thread) Ø 4.5mm - Size (100mm to 250mm) - ,,Schanz Screw (16mm Thread)
	Ø 5.0mm - Size (100mm to 250mm) - "Schanz Screw (16mm Thread) Ø 3.0mm - Size
	(100mm to 250mm) - ,,Schanz Screw (16mm Thread) Ø 4.0mm - Size (100mm to 250mm) -
	"Schanz Screw (32mm Thread) Ø 2.0mm - Size (100mm to 250mm) - "Schanz Screw (32mm
	Thread) Ø 2.5mm - Size (100mm to 250mm) - ,,Schanz Screw (32mm Thread) Ø 4.5mm -
	Size (100mm to 250mm) - ,,Schanz Screw (32mm Thread) Ø 3.5mm - Size (100mm to
	250mm) - Schanz Screw (32mm Thread) Ø 5.0mm - Size (100mm to 250mm), Schanz Screw
	(32mm Thread) Ø 3.0mm - Size (100mm to 250mm) - ,,Schanz Screw (32mm Thread) Ø 4.0
	mm - Size (100mm to 250mm) - "Schanz Screw (50mm Thread) Ø 3.5mm - Size (100mm to
	250mm) - "Schanz Screw (50mm Thread) Ø 4.5mm - Size (100mm to 250mm) - "Schanz
	Screw (50mm Thread) Ø 5.0mm - Size (100mm to 250mm) - ,,Schanz Screw (50mm Thread)
	Ø 3.0mm - Size (100mm to 250mm) - "Schanz Screw (50mm Thread) Ø 4.0mm - Size
	(100mm to 250mm) - "Schanz Screw (16mm Cancellous Threaded) - Ø 3.5/4.5,6.5/4.5 - Size
	(100mm to 250mm) - ,,Schanz Screw (32mm Cancellous Threaded) Ø 3.5/4.5 - ,,6.5/4.5 -
	Size (100mm to 250mm) - ,,Schanz Screw (50mm Cancellous Threaded) Ø 3.5/4.5 - ,,6.5/4.5
	- Size (100mm to 250mm) - ,,Schanz Screw (32mm Tapper Threaded) Ø 6.0mm - Size
	(100mm to 250mm) - ,,Schanz Screw (50mm Tapper Threaded) Ø 6.0mm - Size (100mm to
	250mm) - ,,6.5mm - ,,7.5mm - Size (30mm to 50mm) - ,,Pre Bend Connecting Rod (MIS) 5.5
	mm - Size (35mm to 150mm) - CAGE / SPACERTLIF (Transformational Lumbar Interbody
	Fusion) Bullet Cage 25mm,30mm - Size (7mm to 12mm) - ,,TLIF (Transformational Lumbar
	Interbody Fusion) Kidney Cage 04° - ,,08° - ,,11° - Size (7mm to 12mm) - ,,PLIF (Posterior
	Lumbar Interbody Fusion) Cage 20mm - ,,25mm - Size (7mm to 12mm) - ,,Mesh Cage Ø
	10mm - ,,12mm - ,,14mm - ,,16mm - ,,18mm - ,,20mm - Size (50mm - ,,100mm) - ,,
	Expandable Cage Ø 12mm - ,,14mm - ,,16mm - ,,18mm - ,,20mm - Size (20mm to 75mm) - ,
	CERVICLE PLATE & SCREW Cervical Plate - Size (22mm to 60mm) - ,,Cervical Bone Screw
	Size (10mm to 18mm) - ,,Cervical Revision Bone Screw - Size (10mm to 18mm) - ,,Self-
	Drilling Cervical Bone Screw - Size (10mm to 18mm) - Anterior Cervical Interbody Fusion
	Cage 12mm,14mm - ,,16mm - Size (4mm to 7mm) - ,,Cervical Impacted Fusion Cage 14mm
	- "16mm - Size (mm to 8mm) - "Posterior Multiaxial Cancellous Screw (Lateral Mass) 3.5
	mm - ,,4.0mm - Size (14mm to 32mm) - ,,Connecting Rod (PMCS) Ø 3.2mm - Size (25mm to
	200mm) - ,,Posterior Hook Ø 3.2mm - Size (4.5mm - ,,6.0mm) - ,,Posterior Connector 3.2
	mm - "5.0mm - Size (9mm to 15mm) - "Posterior Occipital T Plate - Size (32mm to 44mm) -
	"Posterior Occipital Y Plate (With Connector Set) - Size (32mm to 44mm) - Posterior
	Occipital Cancellous Screw - Size (12mm),Posterior Occipital Connecting Rod (Bend) 3.2mm
	- Size (65mm to 85mm) - ,,Posterior Occipital Combi. Connecting Rod (Step Rod) 3.2 mm
	(150 mm) x 5.5 mm (270 mm) - Size () - ,,Posterior Occipital Plate with Rod 3.2 mm x 250
	mm - Size (4 Hole) - ,

<u> </u>	1. Generic Name : ARTHROSCOPY IMPLANTS
6	2. Brand Name :SPLINT
	3. Notified Category :Orthopaedic Implants
	4. Class of Medical Device : Class C
	5. Shelf life :NIL
	6. Sterile/Non-Sterile:Non-Sterilized
	7. 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.
	8. Material of Construction: Stainless Steel 316L, Titanium
	9. Dimension: Various Dimensions
	10. Model/Catalogue No./Name : ACL Screw (Cannulated Interference Screw) - Ø 7mm,
	8mm, 9mm, 10mm, 11mm - Size (20mm to 35mm), Endobutton With Loop - Size (10mm to
	35mm), Endobutton, Suture Disc, Suture Anchor Screw Loaded - Size (Ø 3.0mm, 5.0mm),
	Suture Anchor Screw Loaded with Needle - Size (Ø 3.0mm, 5.0mm), U Staple, Suture
	Anchor Screw - Size (Ø 3.0mm, 5.0mm), Fier Wire with Needle, Knotless Suture Anchor
	Screw Loaded, Spiked Washer, Tibial Post Fixation Screw, 6.5mm, Ligament Spiked Staple,
	Tibial Attachable Disk, Endobutton With Adjustable Loop, Cancellous Screw Low Profile 4.0
	mm, Cancellous Screw Low Profile 6.5mm, Healfix PEEK Anchor, PEEK Anchor Loop,
	WasherLoop, Washer with Button, ABS Button, Tighrope Button Extender



7	1. Generic Name : CRANIO-MAXILLOFACIAL IMPLANT
•	2. Brand Name :SPLINT
	3. Notified Category :Orthopaedic Implants
	4. Class of Medical Device :Class C
	5. Shelf life :NIL
	6. Sterile/Non-Sterile:Non-Sterilized
	<b>7. Intended Use</b> :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.
	8. Material of Construction: Stainless Steel 316L, Titanium
	9. Dimension: Various Dimensions
	10. Model/Catalogue No./Name : Mini Screws (Single Slot Head) 1.5 mm - Size (4mm to
	16mm) - Mini Screws (Single Slot Head) 2.5 mm - Size (4mm to 18mm), Mini Screws (Single
	Slot Head) 2.0 mm - Size (4mm to 16mm), Mini Screws (Cross Slot Head) 1.5 mm - Size
	(4mm to 16mm), Mini Screws (Cross Slot Head) 2.0 mm - Size (4mm to 16mm) - Mini Screws
	(Cross Slot Head) 2.5 mm - Size (4mm to 18mm), Mandible Plate 1.5mm - Size (4 Hole to 30
	Hole), Mandible Plate 2.0mm - Size (4 Hole to 30 Hole), Mandible Plate 2.5mm - Size (4
	Hole to 30 Hole), Mandible Plate with Center Space 1.5mm - Size (2 Hole to 6 Hole),
	Mandible Plate with Center Space 2.0mm - Size (2 Hole to 6 Hole), Mandible Plate with
	Center Space 2.5mm - Size (2 Hole to 6 Hole), Orbital Plate 1.5mm - Size (4 Hole to 10
	Hole), Orbital Plate 2.0mm - Size (4 Hole to 10 Hole), Orbital Plate 2.5mm - Size (4 Hole to
	10 Hole) - Orbital Plate with Center Space 1.5mm - Size (4 Hole to 8 Hole), Orbital Plate
	with Center Space 2.0mm - Size (4 Hole to 8 Hole), Orbital Plate with Center Space 2.5mm -
	Size (4 Hole to 8 Hole), L Shape Plate 1.5mm x 02 Hole (Left & Right) - Size (2 Hole, 3 Hole),
	L Shape Plate 2.0mm x 02 Hole (Left & Right) - Size (2 Hole, 3 Hole), L Shape Plate 2.5mm k
	02 Hole (Left & Right) - Size (2 Hole, 3 Hole), L Shape Plate 1.5mm x 03 Hole (Left & Right)
	Size (3 Hole), L Shape Plate 2.0mm x 03 Hole (Left & Right) - Size (3 Hole) - L Shape Plate 2.5
	mm x 03 Hole (Left & Right) - Size (3 Hole), L Shape Plate 1.5mm With Space 02 Hole (Left &
	Right) - Size (2 Hole, 3 Hole), L Shape Plate 2.0mm With Space 02 Hole (Left & Right) - Size
	(2 Hole, 3 Hole), L Shape Plate 2.5mm With Space 02 Hole (Left & Right) - Size (2 Hole, 3
	Hole), L Shape Plate 1.5mm With Space 03 Hole (Left & Right) - Size (3 Hole), L Shape Plate
	2.0mm With Space 03 Hole (Left & Right) - Size (3 Hole), L Shape Plate 2.5mm With Space
	03 Hole (Left & Right) - Size (3 Hole), L Shape 120° Oblique Angle Plate 1.5mm x 02 Hole
	(Left & Right) - Size (2 Hole, 3 Hole), L Shape 120° Oblique Angle Plate 2.0mm x 02 Hole
	(Left & Right) - Size (2 Hole, 3 Hole) - L Shape 120° Oblique Angle Plate 2.5mm x 02 Hole
	(Left & Right) - Size (2 Hole, 3 Hole), L Shape 120° Oblique Angle Plate 1.5mm x 03 Hole
	(Left & Right) - Size (3 Hole), L Shape 120° Oblique Angle Plate 2.0mm x 03 Hole (Left &
	Right) - Size (3 Hole), L Shape 120° Oblique Angle Plate 2.5mm x 03 Hole (Left & Right) -
	Size (3 Hole), L Shape 150° Oblique Angle Plate 1.5mm x 02 Hole (Left & Right) - Size (2
	Hole, 3 Hole), L Shape 150° Oblique Angle Plate 2.0mm x 02 Hole (Left & Right) - Size (2
	Hole, 3 Hole), L Shape 150° Oblique Angle Plate 2.5mm x 02 Hole (Left & Right) - Size (2
	Hole, 3 Hole), L Shape 150° Oblique Angle Plate 1.5mm x 03 Hole (Left & Right) - Size (3
	Hole), L Shape 150° Oblique Angle Plate 2.0mm x 03 Hole (Left & Right) - Size (3 Hole) - L
	Shape 150° Oblique Angle Plate 2.5mm x 03 Hole (Left & Right) - Size (3 Hole), T Shape
	Plate Head 2 Hole x 1.5mm - Size (2 Hole, 3 Hole), T Shape Plate Head 2 Hole x 2.0mm -
	Size (2 Hole, 3 Hole), T Shape Plate Head 2 Hole x 2.5mm - Size (2 Hole, 3 Hole), T Shape
	Plate Head 3 Hole x 1.5mm - Size (3 Hole), T Shape Plate Head 3 Hole x 2.0mm - Size (3
	Hole), T Shape Plate Head 3 Hole x 2.5mm - Size (3 Hole), T Shape Plate Head 2 Hole With
	Space 1.5mm - Size (2 Hole, 3 Hole), T Shape Plate Head 2 Hole With Space 2.0mm - Size [2
	Hole, 3 Hole), T Shape Plate Head 2 Hole With Space 2.5mm - Size (2 Hole, 3 Hole), T Shape
	Plate Head 3 Hole With Space 1.5mm - Size (3 Hole), T Shape Plate Head 3 Hole With Space
	2.0mm - Size (3 Hole),T Shape Plate Head 3 Hole With Space 2.5mm - Size (3 Hole) - X
	Shape Plate 1.5mm - Size (5 Hole), X Shape Plate 2.0mm - Size (5 Hole), X Shape Plate 2.5
	mm - Size (5 Hole), Y Shape Plate 1.5mm - Size (4 Hole, 5 Hole), Y Shape Plate 2.0mm - Size
	(4 Hole, 5 Hole), Y Shape Plate 2.5mm - Size (4 Hole, 5 Hole), Y Shape Plate With Space 1.5
	mm - Size (4 Hole, 5 Hole), Y Shape Plate With Space 2.0mm - Size (4 Hole, 5 Hole), Y Shape
	Plate With Space 2.5mm - Size (4 Hole, 5 Hole), Double Y Shape Plate 1.5mm - Size (6 Hole),
	Double Y Shape Plate 2.0mm - Size (6 Hole), Double Y Shape Plate 2.5mm - Size (6 Hole),
	Shape Plate 1.5mm (Left & Right) - Size (4 Hole) - Z Shape Plate 2.0mm (Left & Right) - Size
	(4 Hole), Z Shape Plate 2.5mm (Left & Right) - Size (4 Hole), Curved Plate 1.5mm (Left &
	Right) - Size (6 Hole), Curved Plate 2.0mm (Left & Right) - Size (6 Hole), Curved Plate 2.5mm
	(Left & Right) - Size (6 Hole), Nose H Shape Plate 1.5mmNose H Shape Plate 2.0mmNose H
	Shape Plate 2.5mmNose Y Shape Plate 1.5mmNose Y Shape Plate 2.0mmNose Y Shape
	Plate 2.5mmChin Plate 2.0mmI Shape Plate 1.5mmI Shape Plate 2.0mmI Shape Plate 2.5
	mm3D Plate 2.0mm - Size (4 Hole, 6Hole, 8 Hole, 16 Hole), TMJ Plate 2.5mm (Left & Right) -
	Size (20 Hole to 28 Hole) - Reconstruction Plate Angled 2.5mm (Left & Right) - Size (20 Hole
	to 28 Hole), Reconstruction Plate Angled 2.7mm (Left & Right) - Size (20 Hole to 28 Hole),
	Reconstruction Plate For Mandible Straight 2.7mm - Size (8 Hole to 30 Hole),

	Reconstruction Plate For Mandible Double Angled 2.7mm - Size (16 Hole to 24 Hole),
	Reconstruction Plate For Mandible U Shape 2.7mm - Size (14 Hole, 16 Hole), Easy Mesh 1.5
	mm - Size (50mm x 50mm to 15mm x 150mm), Easy Mesh 2.0 mm - Size (50mm x 50mm
	to 15mm x 150mm), Easy Mesh 1.5 mm (PRE-BEND) - Size (50mm x 50mm to 15mm x
	150mm), Easy Mesh 2.0 mm (PRE-BEND) - Size (50mm x 50mm to 15mm x 150mm), Wire
	Mesh 1.5 mm - Size (50mm x 50mm to 15mm x 150mm) - Wire Mesh 2.0 mm - Size (50mm
	x 50mm to 15mm x 150mm), Emergency Screws (Single Slot Head) 1.7 mm - Size (6mm to
	14mm), Emergency Screws (Single Slot Head) 2.3 mm - Size (6mm to 14mm), Emergency
	Screws (Single Slot Head) 2.7 mm - Size (6mm to 14mm), Emergency Screws (Cross Slot
	Head) 1.7 mm - Size (6mm to 14mm), Emergency Screws (Cross Slot Head) 2.3 mm - Size
	(6mm to 14mm), Emergency Screws (Cross Slot Head) 2.7 mm - Size (6mm to 14mm), Self-
	Drilling Screws (Cross Slot Head) 1.5 mm - Size (3mm to 14mm), Self-Drilling Screws (Cross
	Slot Head) 2.0 mm - Size (3mm to 14mm) - Self-Drilling Screws (Cross Slot Head) 2.5 mm -
	Size (3mm to 14mm), Burr Hole Plate 1.5 mm - Size (22.5mm, 28mm), Orbital Floor Plate
	1.5 mm - Size (Small, Medium, Large), Burr Hole Plate 2.0 mm - Size (22.5mm, 28mm),
	Orbital Floor Plate 2.0 mm - Size (Small, Medium, Large), Mastoid Mesh Plate 1.5 mm - Size
	(Small, Medium, Large), Mastoid Mesh Plate 2.0 mm - Size (Small, Medium, Large)
8	1. Generic Name : HIP REPLACEMENT SYSTEM
0	2. Brand Name :SPLINT
	3. Notified Category :Orthopaedic Implants
	4. Class of Medical Device :Class D
	5. Shelf life :NIL
	6. Sterile/Non-Sterile:Non-Sterilized
	7. Intended Use : Total 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.
	8. Material of Construction: Stainless Steel 316L, Titanium
	9. Dimension: Various Dimensions
	<b>10. Model/Catalogue No./Name :</b> Hip Cement Restrictor - Thompson Prosthesis - Size (Ø
	37mm to 55mm),Austin Moore Prosthesis - Size (Ø 37mm to 55mm) - ,,Austin Moore
	Prosthesis (Narrow Stem) - Size (Ø 37mm to 55mm) - ,,Bipolar Prosthesis (FENESTRATED) -
	Size (Ø 37mm to 55mm),Bipolar Prosthesis (NON-FENESTRATED) - Size (Ø 37mm to 55mm
	- ,,Modular Bipolar Head (-6mm - ,,-3mm - ,,0mm - ,,+3mm - ,,+6mm) - Size (Ø 37mm to
	55mm) - "Muller Stem - Size (130mm to 160mm) - "Muller Uncoated Stem - Size (130mm
	to 160mm) - "Standard Stem - Size (130mm to 160mm) - "Quixotic Uncemented Stem -
	Size (120mm to 150mm) - ,,Quixotic Uncemented (HA Coated) Stem - Size (120mm to
	150mm) - ,,Ring Lock Modular Head - Size (Ø 41mm to 55mm),Modular Internal Head
	(External Tapper) Ø 28mm - Size ((-6mm - ,,-3mm - ,,0mm - ,,+3mm - ,,+6mm)) - ,,Modular
	Internal Head (Internal Tapper) Ø 22mm - ,,28mm - ,,32mm - ,,36mm - Size ((-5mm - ,,-3
	mm - ,,0mm - ,,+3mm - ,,+5mm)) - ,,Standard Long Stem Ø 9mm - ,,10mm - ,,11mm - ,,
	12mm - ,,- Size (225mm to 300mm) - ,,Standard Long Stem Uncemented Ø 9mm - ,,10mm -
	,,11mm - ,,12mm - ,,13mm - ,,- Size (225mm to 300mm) - ,,Acetabular Cup - Ø 28mm,
	32mm - Size (Ø 40mm to 56mm) - ,,Uncemented Cup Shell (40 to 60) - Size (Ø 40mm to
	60mm) - ,,Liner Cup Ø 22 - ,,28 - ,,32 - ,,36 - Size (Ø 40mm to 60mm) - ,,Hip Screw 6.5mm -
	Size (20mm to 50mm) - ,,Centraliser - Size (Ø 9 - ,,10 - ,,11) - ,,Redial Head Prosthesis Ø
	16mm - ,,18mm - ,,20mm - ,,22mm - ,,24mm - Size (6mm to 8mm) - ,
9	1. Generic Name : SHOULDER PROSTHESIS
	2. Brand Name :SPLINT
	3. Notified Category :Orthopaedic Implants
	4. Class of Medical Device : Class C
	5. Shelf life :NIL
	6. Sterile/Non-Sterile:Non-Sterilized
	7. Intended Use : Shoulder System is intended for use as an orthopedic implant for partial
	or total shoulder arthroplasty to treat the following:significant disability in degenerative,
	rheumatoid, or traumatic disease of the glenohumeral joint, united humeral head
	fractures of long duration, irreducible 3- and 4-part proximal humeral fractures, avascular
	necrosis of the humeral head.
	8. Material of Construction: Stainless Steel 316L, Titanium
	9. Dimension: Various Dimensions
	<b>10. Model/Catalogue No./Name :</b> Shoulder Prosthesis - Size (Ø 35mm to 43mm),Shoulder
	Cup - Size (Ø 35mm to 43mm) - "Shoulder Neck ShaftShoulder Stem Ø 6mm - "7mm - "
	8mm - Size (100mm - ,,120mm) - ,,Shoulder Prosthesis - Dia. (Ø) 37.0 mm to 41.0 mm,
	Radial Head Prosthesis (Radial Head) - Dia. ( $\emptyset$ ) 14.0 mm to 30.0 mm – Sizes (+4 - ,,+2 - ,,0
	,) - ,,Radial Head Prosthesis (Radial Stem) - Dia. ( $\emptyset$ ) 3.5 mm to 13.5 mm – Sizes (+4 - ,,+2 - ,
	0 - ,,) - ,,Radial Head Prosthesis (Radial Stem HA Coated) - Dia. (Ø) 3.5 mm to 13.5 mm Sizes
1	(14, 12, 12) Badial Head Prosthesis (Radial Stein TA Coaled) - Dia. (9) 5.5 mm to 75.5 mm to 20.0 mm

is earlier.

Competent Authority

