



online

3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia
SKTC-113 and Notified Body No. 2265

EC Certificate

No. 2017-MDD/QS-010

issued in compliance with the Council Directive 93/42/EEC as amended by 2007/47/EC,
which is implemented by the Slovak Government Order No. 582/2008 (Collection of Laws),
certifies that the medical devices of Class IIb

(49-SD)853 Orthopaedic Implants & Spinal Implants (1-48)852854855
Product Types: Interlocking Nails, Locking Plates, Locking Screws, Bone Plates,
Bone Screws, Arthroscopy Implants
Brand Name: SSEPL
(for detailed list refer to Annex; page 1 to 5)

manufactured by company

Sharma Surgical & Engg. Pvt. Ltd.

Office: 1st Floor, Girikandra Complex, Near HDFC ATM, Opp-Bapod Talav,
Waghodia road, Vadodara-390019, Gujarat, India
Works: 654 & 655 GIDC ESTATE, Waghodia-391760, Dist.: Vadodara, India

is manufactured under conditions fulfilling the quality system requirements of Annex II,
Section 3.2. of the Directive 93/42/EEC as amended by 2007/47/EC..

The Notified Body No. 2265 has performed an audit of the above products quality system. The full quality assurance system has been assessed, approved and is subject to continuous surveillance according to Annex II, Sections 3.3 and 5, of the Directive 93/42/EEC as amended 2007/47/EC. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Final protocol No. 310056/2017 that is enclosed to this certificate.

This certificate is issued under the following conditions:

It applies only to the quality system maintained in the manufacture of the above referenced model of medical device and it does not substitute the design or type-examination procedures, if requested. The certificate remains valid until the manufacturing conditions or the quality system are changed but until May 7th, 2022 at the latest. The certificate validity is conditioned upon positive results of surveillance audits. After fulfilling the relevant EU legislation requirements, the manufacturer shall affix to each in vitro diagnostic medical device, of the above referenced model, the CE-marking followed by the number of the Notified Body.

At Bratislava on May 8th, 2017



Dr. Katarína Srdošová
Responsible to act on behalf of NB 2265



ANNEX TO EC CERTIFICATE No. 2017-MDD/QS-201

issued for the company

Sharma Surgical & Engg. Pvt. Ltd.

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Vadodara-390019, Gujarat, India

Works: 654 & 655 GIDC ESTATE, Waghodia-391760, Dist.: Vadodara, India

List of medical devices covered by the EC Certificate:

CAT. NO.	BRAND NAME	TYPE	DIA	LENGTH/HOLES
Interlocking Nail with Nail Cap & Accessories				
SSEPL 001	SSEPL	IMSC Nail A-B	09-13mm	15 to 30
SSEPL 002	SSEPL	Ankle Arthrodesis Nail	09-12mm	15 to 35
SSEPL 003	SSEPL	D-IMSC Nail	10-13mm	15 to 30
SSEPL 004	SSEPL	Easy Universal Femur Nail	09-12mm	30 to 44
SSEPL 005	SSEPL	Easy Universal Tibia Nail	08-11mm	26 to 40
SSEPL 006	SSEPL	Ender Nail (3.5mm)	02-05mm	44cm
SSEPL 007	SSEPL	Femur Antigrade Nail 130DG	09-12mm	30 to 44
SSEPL 008	SSEPL	Femoral Nail	09-12mm	30 to 44
SSEPL 009	SSEPL	G.K. UNI Tibia Nail	08-11mm	26 to 40
SSEPL 010	SSEPL	Humerus Antigrade Nail 130DG	06-09mm	20 to 30
SSEPL 011	SSEPL	SSEPL Humerus Nail - One Hole	06-09mm	20 to 30
SSEPL 012	SSEPL	Humerus Nail - Three Holes	06-09mm	20 to 30
SSEPL 013	SSEPL	Gen Nail	09-12mm	18 to 44
SSEPL 014	SSEPL	Proximal Humerus Locked Nail	06-09mm	16cm
SSEPL 015	SSEPL	Proximal Humerus Nail	06-09mm	16cm
SSEPL 016	SSEPL	Radius-Ulna Nail	03.4-5mm	14 to 30
SSEPL 017	SSEPL	Reconstruction Nail	09-12mm	30 to 44
SSEPL 018	SSEPL	Retrograde Femur Nail	09-12mm	30 to 44
SSEPL 019	SSEPL	Subtrochanteric Trochanteric Nail 1200G (SSTN)	10-13mm	24 to 44
SSEPL 020	SSEPL	Stander Femoral Nail	09-12mm	30 to 44
SSEPL 021	SSEPL	Subtrochanteric Nail DG 135	10-13mm	24 to 44
SSEPL 022	SSEPL	Supracondylar Nail	10-13mm	15 to 30
SSEPL 023	SSEPL	Supracondylar Locked Nail	10-13mm	15 to 30
SSEPL 024	SSEPL	Tibia Nail	08-11mm	26 to 40
SSEPL 025	SSEPL	Universal Femoral Nail	08-11mm	30 to 44
SSEPL 026	SSEPL	Universal Tibia Nail	08-11mm	26 to 40
SSEPL 027	SSEPL	Expert Tibia Nail	08-11mm	26 to 40
SSEPL 028	SSEPL	O-IMSC Locked Nail	10-13mm	15 to 30
Bone Plates & Bone Screws				
SSEPL 101	SSEPL	Anatomical Proximal Humerus (DC)	3.5mm, 4.5mm	4 to 12
SSEPL 102	SSEPL	Angle Blade Plate		02 to 18
SSEPL 103	SSEPL	DCP Plate (Narrow)		02 to 16

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CAT. NO.	BRAND NAME	TYPE	DIA	LENGTH/HOLES
Bone Plates & Bone Screws				
11	SSEPL 104	SSEPL DCS Plate 95DG		02 to 18
	SSEPL 105	SSEPL DHS Long Barrel (DC Hole)		02 to 16
	SSEPL 106	SSEPL DHS Long Barrel (RH)		02 to 16
13	SSEPL 107	SSEPL DHS Short Barrel (DC Hole)		02 to 16
	SSEPL 108	SSEPL DHS Short Barrel (Round Hole)		02 to 16
	SSEPL 109	SSEPL Distal Tibia Anatomical Plate		02 to 12
	SSEPL 110	SSEPL H- Plate		14 to 40mm
	SSEPL 111	SSEPL K- Plate (11 Holes)		02 to 14
829	SSEPL 112	SSEPL L- Buttress Plate		03 to 12
	SSEPL 113	SSEPL LC DCP Broad		03 to 18
18	SSEPL 114	SSEPL Small T- Plate		02 to 12
	SSEPL 115	SSEPL Mini L- Plate (7 Holes)		03 to 12
24	SSEPL 116	SSEPL Narrow LC DCP (8 Holes)		04 to 13
	SSEPL 117	SSEPL Oblique T- Plate (2 Holes)		02 to 13
	SSEPL 118	SSEPL One-Third Tubular Plate		04 to 12
	SSEPL 119	SSEPL Reconstruction Plate 4.5mm (RH)		03 to 16
	SSEPL 120	SSEPL Reconstruction Plate 4.5mm (DC)		04 to 16
	SSEPL 121	SSEPL Reconstruction Plate 3.5mm (RH)		04 to 16
	SSEPL 122	SSEPL Reconstruction Plate 3.5mm (DC)		04 to 16
	SSEPL 123	SSEPL DCP Plate Small		02 to 12
	SSEPL 124	SSEPL Small L- Plate (7 Holes)		03 to 12
17	SSEPL 125	SSEPL Small LC DCP (8 Holes)		02 to 12
	SSEPL 126	SSEPL Spoon Plate		04 to 12
584	SSEPL 127	SSEPL Distal Femoral DC Hole		02 to 18
3	SSEPL 128	SSEPL Proximal Femur DC Hole		02 to 12
12	SSEPL 129	SSEPL Calcaneum Plate		S. M. L
	SSEPL 130	SSEPL Cobra Head Plate		02 to 16
7	SSEPL 131	SSEPL DCP Broad Plate		02 to 18
10	SSEPL 132	SSEPL T- Plate (SPS System)		04 to 12
	SSEPL 133	SSEPL T-Buttress Plate		04 to 12
281	SSEPL 134	SSEPL Tibial Lateral Buttress Plate		04 to 16

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CAT. NO.	BRAND NAME	TYPE	DIA	LENGTH/HOLES
Bone Plates & Bone Screws				
14	SSEPL 135	SSEPL Y-Plate		03 to 12
	SSEPL 136	SSEPL Z-Plate		20 to 75mm
	SSEPL 137	SSEPL Calcaneum Locking Plate (D Type)		S, M, L
	SSEPL 138	SSEPL Calcaneum Locking Plate (P Type)		S, M, L
	SSEPL 139	SSEPL Calcival Locking Plate		S, M, L
	SSEPL 140	SSEPL Clover Leaf Locking Plate		04 to 12
	SSEPL 141	SSEPL 2.4 mm L Plate 90°x2x4 Hole		04 Holes
	SSEPL 142	SSEPL 2.4 mm L Plate 90°x3x4 Hole		04 Holes
	SSEPL 143	SSEPL 2.4 mm L Plate 120°x3x4 Hole		04 Holes
	SSEPL 144	SSEPL 2.4 mm Straight Plate		
	SSEPL 145	SSEPL 2.4 mm T Plate 3x4 Hole		
	SSEPL 146	SSEPL 2.4 mm Volar Juxta Plate 5X4		
33824	SSEPL 147	SSEPL Distal Tibia Anatomical Locking Plate		02 to 12
26	SSEPL 148	SSEPL Femoral Condylar Locking Plate		04 to 16
25	SSEPL 149	SSEPL DCP Broad Locking Plate		04 to 18
	SSEPL 150	SSEPL DHS Locking Plate		04 to 18
27828	SSEPL 151	SSEPL Distal Femoral Locking Plate		02 to 12
	SSEPL 152	SSEPL Distal Humerus Locking Plate		02 to 12
	SSEPL 153	SSEPL Distal Radius Plate (LCP)		02 to 12
	SSEPL 154	SSEPL Distal Medial Humerus Locking Plate		02 to 12
1832	SSEPL 155	SSEPL Distal Medial Tibial Locking Plate		02 to 12
	SSEPL 156	SSEPL L-Buttress Locking Plate		02 to 12
21822	SSEPL 157	SSEPL L Locking Plate		02 to 12
29830	SSEPL 158	SSEPL Lateral Tibia Locking Plate		02 to 18
35836	SSEPL 159	SSEPL Low Profile Proximal Humerus Locking Plate		02 to 12
19820	SSEPL 160	SSEPL Oblique T-Plate		02 to 12
	SSEPL 161	SSEPL Olecranon Locking Plate		04 to 12
	SSEPL 162	SSEPL One-Third Tubular Plate		04 to 12
	SSEPL 163	SSEPL Proximal Humerus Plate (LCP)		03 to 16
16	SSEPL 164	SSEPL Reconstruction Plate (LCP) (3.5mm)		03 to 16
	SSEPL 165	SSEPL Reconstruction Plate (LCP) (4.5mm)		03 to 16

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CAT. NO.	BRAND NAME	TYPE	DIA	LENGTH/HOLES
Bone Plates & Bone Screws				
23	SSEPL 166	SSEPL	Semi Tubular Plate (6 Hole)	03 to 12
38	SSEPL 167	SSEPL	T-Buttress Plate (LCP)	04 to 12
37	SSEPL 168	SSEPL	T-Locking Plate	02 to 12
30240	SSEPL 169	SSEPL	Y-Plate (DC)	03 to 12
47	SSEPL 201	SSEPL	3.5 Cortical Screw (14TPI&20TPI)	10 to 50mm
47	SSEPL 202	SSEPL	4.5 mm Cortical Screw	10 to 50mm
47	SSEPL 203	SSEPL	4mm Cancellous Screw (Full, 16, 32, Thread)	10 to 60mm
47	SSEPL 204	SSEPL	4mm Cancellous Screw (Cannulated)	20 to 75mm
47	SSEPL 205	SSEPL	5mm Cancellous Screw (Cannulated)	20 to 75mm
47	SSEPL 206	SSEPL	6.5mm Cancellous Screw (Full, 16, 32, Thread)	25 to 120mm
47	SSEPL 207	SSEPL	6.5mm Cancellous Screw (Cannulated) (16, 32, Full Thread)	25 to 120mm
47	SSEPL 208	SSEPL	7mm Cancellous Screw (Cannulated)	25 to 120mm
47	SSEPL 209	SSEPL	8mm Cancellous Screw (Cannulated)	25 to 120mm
47	SSEPL 210	SSEPL	DHS Compression Screw	50 to 120mm
47	SSEPL 211	SSEPL	Malleolar Screw (4.5mm)	25 to 75mm
47	SSEPL 212	SSEPL	3.7mm Shack Thread	16 to 36mm
47	SSEPL 213	SSEPL	3 mm Locking Bolt	18 to 30mm
47	SSEPL 214	SSEPL	3mm Shack Thread	12 to 32mm
47	SSEPL 215	SSEPL	4 mm Shack Thread	10 to 40mm
47	SSEPL 216	SSEPL	5 mm Shack Thread	18 to 95mm
47	SSEPL 217	SSEPL	6mm Locking Bolt	50 to 120mm
47	SSEPL 218	SSEPL	6mm Locking Bolt (C.C)	50 to 120mm
47	SSEPL 219	SSEPL	8mm Locking Bolt (C.C)	50 to 120mm
47	SSEPL 220	SSEPL	10mm GAM Bolt (C.C)	50 to 120mm
47	SSEPL 221	SSEPL	2.7mm Cortex Locking Screw	12 to 70mm
47	SSEPL 222	SSEPL	4 mm Cancellous Locking Screw	10 to 60mm
47	SSEPL 223	SSEPL	4 mm Universal Cortex Screw	12 to 60mm
47	SSEPL 224	SSEPL	5mm Cancellous Locking Screw	10 to 80mm
47	SSEPL 225	SSEPL	5mm Universal Cortex Screw	12 to 100mm
47	SSEPL 226	SSEPL	6.5mm Cortex Screw (16mm)	50 to 120mm
47	SSEPL 227	SSEPL	Mounting Block (4mm)	Standard
47	SSEPL 228	SSEPL	Mounting Block (5mm)	Standard

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