



#05706
03 MAYIS 2017

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

EC Certificate

No. 2017-MDD/QS-201

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

Orthopaedic Implants & Spinal Implants
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. 310056/2012 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 5th, 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 6th, 2017

AK-TİF TERCÜME
Mühendislik Danışmanlık Hizmetleri
Turizm Gıda Sanayi ve Ticaret Ltd.Şti.
Cayhan Atuf Köhneçioğlu H. 458 8 Bulvarı KAT:1
Tel: 0312 417 79 32 - 472 84 33 Fax: 0312 417 79 45
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Dr. Katarína Srdošová
Responsible to act on behalf of NB 2265
Ankara 17. Noter
Lpza Yetkil Katip
E-Gökhay EKE



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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	Gam 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 120DG (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	D-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	Angio Blade Plate		02 to 18
SSEPL 103	SSEPL	DCP Plate (Narrow)		02 to 16

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Mühendislik Danışmanlık Hizmetleri
Turizm Gıda Sanayi ve Ticaret Ltd.Şti.
Cayhan Atuf Kansu Cad. No: 12/2 Balgat Ankara
Tel: 0312 417 2000-472 84 33 Fax: 0312 417 19 46
E-posta: info@ak-tif.com.tr Web: 011 044 0767

At Bratislava, on May 6th, 2017
Valid until May 5th, 2022

Dr. Katarina Srdošová
Responsible to act on behalf of NB 2265
Ankara 17. Noter
Yetkili Katip
Gökhan EKE



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List of medical devices covered by the EC Certificate:

CAT. NO.	BRAND NAME	TYPE	DIA	LENGTH/HOLES
Bone Plates & Bone Screws				
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
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
SSEPL.112	SSEPL	L- Buttress Plate		03 to 12
SSEPL.113	SSEPL	LC DCP Broad		03 to 18
SSEPL.114	SSEPL	Small T- Plate		02 to 12
SSEPL.115	SSEPL	Mini L- Plate (7 Holes)		03 to 12
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
SSEPL.125	SSEPL	Small LC DCP (8 Holes)		02 to 12
SSEPL.126	SSEPL	Spoon Plate		04 to 12
SSEPL.127	SSEPL	Distal Femoral DC Hole		02 to 18
SSEPL.128	SSEPL	Proximal Femur DC Hole		02 to 12
SSEPL.129	SSEPL	Calcaneum Plate		S, M, L
SSEPL.130	SSEPL	Cobra Head Plate		02 to 16
SSEPL.131	SSEPL	DCP Broad Plate		02 to 18
SSEPL.132	SSEPL	T Plate (SPS System)		04 to 12
SSEPL.133	SSEPL	T-Buttress Plate		04 to 12
SSEPL.134	SSEPL	Tibial Lateral Buttress Plate		04 to 16

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Turizm Gıda Sanayi ve Ticaret Ltd.Şti.
Ceyhan Atuf Karadağ Çarşısı No: 1/202 Balçık/ANKARA
Tel: 0312 417 79 45 / 417 84 33 Fax: 0312 417 79 45
Başkanlık Sicil No: 011 044 9767

At Bratislava, on May 6th, 2017
Valid until May 5th, 2022

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CAT. NO.	BRAND NAME	TYPE	DIA	LENGTH/HOLES
Bone Plates & Bone Screws				
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	Calvical Locking Plate		S, M, L
SSEPL.140	SSEPL	Clover Leaf Locking Plate		04 to 12
SSEPL.141	SSEPL	2.4 mm L Plate 90x2x4 Hole		04 Holes
SSEPL.142	SSEPL	2.4 mm L Plate 90x3x4 Hole		04 Holes
SSEPL.143	SSEPL	2.4 mm L Plate 120x3x4 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		-
SSEPL.147	SSEPL	Distal Tibia Anatomical Locking Plate		02 to 12
SSEPL.148	SSEPL	Femoral Condylar Locking Plate		04 to 16
SSEPL.149	SSEPL	DCP Broad Locking Plate		04 to 18
SSEPL.150	SSEPL	DHS Locking Plate		04 to 18
SSEPL.151	SSEPL	Distal Femoral Locking Plate		04 to 18
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
SSEPL.155	SSEPL	Distal Medial Tibial Locking Plate		02 to 12
SSEPL.156	SSEPL	L- Buttress Locking Plate		02 to 12
SSEPL.157	SSEPL	L Locking Plate		02 to 12
SSEPL.158	SSEPL	Lateral Tibia Locking Plate		02 to 18
SSEPL.159	SSEPL	Low Profile Proximal Humerus Locking Plate		02 to 12
SSEPL.160	SSEPL	Oblique T- Plate		02 to 12
SSEPL.161	SSEPL	Olecranon Locking Plate		02 to 12
SSEPL.162	SSEPL	One-Third Tubular Plate		04 to 12
SSEPL.163	SSEPL	Proximal Humerus Plate (LCP)		04 to 12
SSEPL.164	SSEPL	Reconstruction Plate (LCP) (3.5mm)		08 to 16
SSEPL.165	SSEPL	Reconstruction Plate (LCP) (4.5mm)		08 to 16

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At Bratislava, on May 6th, 2017
Valid until May 5th, 2022

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List of medical devices covered by the EC Certificate:

CAT. NO.	BRAND NAME	TYPE	DIA	LENGTH/HOLES
Bone Plates & Bone Screws				
SSEPL 166	SSEPL	Semi Tubular Plate (6 Hole)		03 to 12
SSEPL 167	SSEPL	T-Buttress Plate (LCP)		04 to 12
SSEPL 168	SSEPL	T-Locking Plate		02 to 12
SSEPL 169	SSEPL	Y-Plate (DC)		03 to 12
SSEPL 201	SSEPL	3.5 Cortical Screw (14TPI&20TPI)		10 to 50mm
SSEPL 202	SSEPL	4.5 mm Cortical Screw		10 to 50mm
SSEPL 203	SSEPL	4mm Cancellous Screw (Full, 16, 32, Thread)		10 to 60mm
SSEPL 204	SSEPL	4mm Cancellous Screw (Cannulated)		20 to 75mm
SSEPL 205	SSEPL	5mm Cancellous Screw (Cannulated)		20 to 75mm
SSEPL 206	SSEPL	6.5mm Cancellous Screw (Full, 16, 32, Thread)		25 to 120mm
SSEPL 207	SSEPL	6.5mm Cancellous Screw (Cannulated) (16, 32, Full Thread)		25 to 120mm
SSEPL 208	SSEPL	7mm Cancellous Screw (Cannulated)		25 to 120mm
SSEPL 209	SSEPL	8mm Cancellous Screw (Cannulated)		25 to 120mm
SSEPL 210	SSEPL	DHS Compression Screw		50 to 120mm
SSEPL 211	SSEPL	Malleolar Screw (4.5mm)		25 to 75mm
SSEPL 212	SSEPL	3.7mm Snack Thread		18 to 36mm
SSEPL 213	SSEPL	3 mm Locking Bolt		18 to 30mm
SSEPL 214	SSEPL	3mm Snack Thread		12 to 32mm
SSEPL 215	SSEPL	4 mm Snack Thread		10 to 40mm
SSEPL 216	SSEPL	5 mm Snack Thread		18 to 96mm
SSEPL 217	SSEPL	6mm Locking Bolt		50 to 120mm
SSEPL 218	SSEPL	6mm Locking Bolt (C.C)		50 to 120mm
SSEPL 219	SSEPL	8mm Locking Bolt (C.C)		50 to 120mm
SSEPL 220	SSEPL	10mm GAM Bolt (C.C)		50 to 120mm
SSEPL 221	SSEPL	2.7mm Cortex Locking Screw		12 to 70mm
SSEPL 222	SSEPL	4 mm Cancellous Locking Screw		10 to 60mm
SSEPL 223	SSEPL	4 mm Universal Cortex Screw		12 to 60mm
SSEPL 224	SSEPL	5mm Cancellous Locking Screw		10 to 80mm
SSEPL 225	SSEPL	5mm Universal Cortex Screw		12 to 100mm
SSEPL 226	SSEPL	6.5mm Cortex Screw (16mm)		50 to 120mm
SSEPL 227	SSEPL	Mounting Block (4mm)		Standard
SSEPL 228	SSEPL	Mounting Block (5mm)		Standard

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Mühendislik Danışmanlık Hizmetleri
Turizm Gıda Sanayi ve Ticaret Ltd.Şti.
Ceyhan Atuf Kışku Caddesi No: 22/2 D: 2
Teft: 0312 417 79 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 00
Bazı: 0312 417 79 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 00
Fax: 0312 417 79 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 00

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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
Spinal Implants				
SSEPL.401	SSEPL	Spondylosithesis Reduction Screw (5mm)	5.5-6.5mm	38 to 54mm
SSEPL.402	SSEPL	Inner Screw	Standard	Standard
SSEPL.403	SSEPL	Leminar Hook Angle Blade	Standard	Standard
SSEPL.404	SSEPL	Leminar Hook Narrow Blade	Standard	Standard
SSEPL.405	SSEPL	Leminar Hook Reduced Distance	Standard	Standard
SSEPL.406	SSEPL	Leminar Hook Wide Blade	Standard	Standard
SSEPL.407	SSEPL	Mono Sacral Screw	5.5-6.5mm	30 to 54mm
SSEPL.408	SSEPL	Pedicle Hook	Standard	Standard
SSEPL.409	SSEPL	Mono Sacral Screw	5.5-6.5mm	30 to 54mm
SSEPL.410	SSEPL	Rod (5mm)	3.0-5.0mm	75 to 300mm
SSEPL.411	SSEPL	Poly Sacral Screw	5.5-6.5mm	30 to 54mm
SSEPL.412	SSEPL	Staple	Standard	Standard
SSEPL.413	SSEPL	Transverse Connector	Standard	Standard
SSEPL.414	SSEPL	Transverse Process Hook (Left)	Standard	Standard
SSEPL.415	SSEPL	Cage	10 - 24mm	20 to 100mm
Arthroscopy Implants, Pin & Wires				
SSEPL.301	SSEPL	Screw 7mm	6.0-9.0mm	20 to 30mm
SSEPL.302	SSEPL	Button	Standard	Standard
SSEPL.303	SSEPL	Denham Pin		3.0 to 5.0mm
SSEPL.304	SSEPL	Disc	Standard	Standard
SSEPL.305	SSEPL	Kirschner Wire (K-Wire)	1.0-4.5mm	6.0 to 12 Inch
SSEPL.306	SSEPL	Knowles Pin	4.0-5.0mm	50 to 120mm
SSEPL.307	SSEPL	Moor's Pin with Two Nuts	2.0-4.5mm	40 to 100mm
SSEPL.308	SSEPL	Square Nail for Sadius	1.5-3.5mm	10 to 30mm
SSEPL.309	SSEPL	Rush Nail	1.5-3.5mm	10 to 30mm
SSEPL.310	SSEPL	Schanz Screw	1.5-6.5mm	100 to 250mm
SSEPL.311	SSEPL	Screw (8mm)	6.0-9.0mm	20 to 30mm
SSEPL.312	SSEPL	Steinman Pin	3.0-6.0mm	6.0 to 12 Inch
SSEPL.313	SSEPL	Traction Screw	4.0-6.5mm	Standard

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Turizm Gıda Sanayi ve Ticaret Ltd.Şti.
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Baskent Vojası Balçova: 011 044 9767

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