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

EC CERTIFICATE

No. 2017-MDD/QS-030

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

Orthopaedic Implants (Prostheses & Joint Replacements)
Brand Name: SPCPL, SHARMA, MADISON
(for detailed list refer to Annex; pages 1 to 16)

manufactured by company

Sharma Pharmaceutical Pvt. Ltd.

Office: 103/104, Girikandra Complex, Bapod Talav, Near HDFC ATM, Waghodia Road, Vadodara-390019, Gujarat, India
Factory: 444, GIDC Estate, Waghodia-391760, Vadodara, Gujarat, 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 device 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 by 2007/47/EC. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Final protocol No. 310067/2017 hat 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 models of medical devices 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 September 16 , 2022 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits. After receiving of the complementary EC Design-Examination Certificate related to the above referenced models, and fulfilling the relevant EU legislation requirements, the manufacturer shall affix to each medical device of the above referenced model, the CE marking followed by the number of the Notified Body.

At Bratislava, on September 17, 2017

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

ANNEX TO EC CERTIFICATE No. 2017 MDD/QS-030

issued for the company

Sharma Pharmaceutical Pvt. Ltd.

Office: 103/104, Girikandra Complex, Bapod Talav, Near HDFC ATM, Waghodia Road, Vadodara-390019, Gujarat, India

Factory: 444, GIDC Estate, Waghodia-391760, Vadodara, Gujarat, India

List of medical devices covered by the EC Certificate:

Product Name	Dia.	Length	Cat. No.	
			Stainless Steel	Titanium
Thompson Prosthesis (*Sterile & Non-sterile*)	43 mm	Standard, Narrow	SP05.PR0030	SP05.PR0093
	44 mm	Standard, Narrow	SP05.PR0031	SP05.PR0094
	45 mm	Standard, Narrow	SP05.PR0032	SP05.PR0095
	46 mm	Standard, Narrow	SP05.PR0033	SP05.PR0096
	47 mm	Standard, Narrow	SP05.PR0034	SP05.PR0097
	48 mm	Standard, Narrow	SP05.PR0035	SP05.PR0098
	49 mm	Standard, Narrow	SP05.PR0036	SP05.PR0099
	50 mm	Standard, Narrow	SP05.PR0037	SP05.PR0100
	51 mm	Standard, Narrow	SP05.PR0038	SP05.PR0101
	52 mm	Standard, Narrow	SP05.PR0039	SP05.PR0102
	53 mm	Standard, Narrow	SP05.PR0040	SP05.PR0103
	54 mm	Standard, Narrow	SP05.PR0041	SP05.PR0104
	55 mm	Standard, Narrow	SP05.PR0042	SP05.PR0105
Bi-Polar Prosthesis (*Sterile*)	35 mm	Std.	SP05.PR0043	SP05.PR0106
	36 mm	Std.	SP05.PR0044	SP05.PR0107
	37 mm	Std.	SP05.PR0045	SP05.PR0108
	38 mm	Std.	SP05.PR0046	SP05.PR0109
	39 mm	Std.	SP05.PR0047	SP05.PR0110
	40 mm	Std.	SP05.PR0048	SP05.PR0111
	41 mm	Std.	SP05.PR0049	SP05.PR0112
	42 mm	Std.	SP05.PR0050	SP05.PR0113
	43 mm	Std.	SP05.PR0051	SP05.PR0114
	44 mm	Std.	SP05.PR0052	SP05.PR0115
	45 mm	Std.	SP05.PR0053	SP05.PR0116
	46 mm	Std.	SP05.PR0054	SP05.PR0117
	47 mm	Std.	SP05.PR0055	SP05.PR0118
	48 mm	Std.	SP05.PR0056	SP05.PR0119
	49 mm	Std.	SP05.PR0057	SP05.PR0120
	50 mm	Std.	SP05.PR0058	SP05.PR0121
	51 mm	Std.	SP05.PR0059	SP05.PR0122

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At Bratislava, on September 17, 2017
Valid until September 16, 2022

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