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

EC CERTIFICATE

No. 2017-MDD/QS-032

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 IIb,

Orthopaedic Implants & Spinal Implants
(Sterile / Non-Sterile)
Brand Name: SHARMA
(for detailed list refer to Annex; pages 1 to 129)

manufactured by company

Sharma Ortho System Pvt. Ltd.

Factory: 641, 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 2007/47/EC.

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 September 23, 2022 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits. After 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 24, 2017

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