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Location: Moldova

Certificate of Compliance

CE

We hereby declare that the technical file of product complied with the requirement of Council Directive on Medical Devices 93/42/EEC as Amended 2007/47/EC.

Certificate No.: CE-10098

Manufacturer

Name : **SHARMA ORTHO SYSTEM PVT. LTD.**

Address : **445/A, G.I.D.C. Estate, Waghodia, Vadodara-391760, Gujarat, India.**

Products

Name : Orthopaedic Instruments & Surgical Appliances class I

Details : Orthopaedic Instruments & Surgical Appliances as per Section 03 of TCF/01

The Certification body has performed an audit of the above product quality system covering the design, manufacture and final inspection of the certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to Directive Medical Devices Directive (93/42/EEC) as Amended 2007/47/EC.

This certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type-examination procedures, if requested.
2. The certificate remains valid until the manufacturing conditions or the quality systems are changed.
3. The certificate validity is conditioned by positive results or surveillance audits.

The CE mark as shown above can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of conformity and compliance with all relevant EC Directives. The statement is based on a single evaluation of one sample of above mentioned product. It does not imply an assessment of the whole production

Validity of this certificate can be verified at www.ukcertifications.org.uk/verify

Date of Certification	9th August 2019
1st Surveillance Audit Due	8th August 2020
2nd Surveillance Audit Due	8th August 2021
Certificate Expiry (subject to the company maintaining its system to the required standard)	8th August 2022

Authorised Signatory

UK Certification & Inspection Ltd.

71-75 Shelton Street, Covent Garden, London, WC2H 9JQ, United Kingdom
Website:- www.ukcertifications.org.uk, email:- info@ukcertifications.org.uk
Company No. 11847851