



# Declaration of Conformity



Confirms that the products -medical devices of class IIB & IIA models according to the Council Directive 93/42/EEC

Certificate No.: CE-1073

Manufacturer : ORTHO SURGICAL COMPANY  
Address : 520, 5<sup>TH</sup> FLOOR, KIRTI SHIKHAR BUILDING, DISTRICT CENTRE, JANAK PURI, NEW DELHI-110058 (INDIA)  
Product : ORTHOPAEDIC IMPLANTS & INSTRUMENTS  
Product Description : For detailed specification refer to Appendix page 1

Complies with the requirements applicable to it

The manufacturer's technical documentation, as required for Annex II, Section 3.2 of the directive 93/42/EEC, as amended.  
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 validity is conditioned by positive results of surveillance audits  
The statement is based on a single evaluation of one sample of above mentioned products. It does not imply an assessment of the whole production.

Validity of this certificate can be verified at [www.ukcertifications.co.uk/verify](http://www.ukcertifications.co.uk/verify)

Date of initial registration 30<sup>th</sup> June 2010  
Date of this certificate 30<sup>th</sup> June 2010  
Certificate expiry 29<sup>th</sup> June 2011  
Recertification due (subject to the company maintaining its system to the required standard) 29<sup>th</sup> June 2013

*David..*  
Authorised Signatory



This certificate is the property of UK Certification & Inspection Limited and shall be returned immediately on request.  
5 Jupiter House, Calleva Park, Aldermaston, Reading Berkshire RG7 8NN, UK  
Website - [www.ukcertifications.co.uk](http://www.ukcertifications.co.uk)



## Certificate of Conformity

## Appendix

Appendix to Certificate no.:- CE-1073

Manufacturer : Ortho Surgical Company  
Product Group: Orthopaedic Implants & Instruments



This certificate referred to above covers the following products like:

- Product Group:
  - Orthopaedic Screws
  - Orthopaedic Plates
  - Orthopaedic Locking Plates & Screws
  - Orthopaedic Nails
  - Orthopaedic Pins & Wires
  - Orthopaedic External Fixators
  - Orthopaedic Prosthesis
  - Orthopaedic Instruments
  - Orthopaedic Conventional Implants
  - Orthopaedic Sets

*David..*  
Authorised Signatory







## QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate No: I/QSC- 3846

### **Kvalitet Veritas Quality Assurance**

This is to certify that the Quality Management System of  
**ORTHO SURGICAL COMPANY**

520, Fifth floor, Kirti Shikhar Bld, District centre, Janakpuri , New Delhi.

Has been found to the Quality Management System Standard

**NS-EN ISO 9001:2008 / ISO 9001:2008**

This certificate is valid for the following product or service range

**To Manufacture, Procure and Supply of Orthopedic Equipments to Include  
Intramedullary locking Nails, bone Plates & screws, Conventional Implants,  
External Fixators, Instruments and Sets and Allied / Connected Product In the  
National and International Markets.**

Valid until: 03, August, 2012\*

Issue Date: 04, August, 2009

Issued by

Authorised signatory KVQA

**The certification scope is accredited by the Norsk Akkreditering of  
Norway with reference to the Parliamentary Proposition no 106  
(1989/90) and Norsk Akkreditering's the status laid down in  
Royal Decree of 7<sup>th</sup> October 1993**

**Accredited by a member of IAF's MLA for Quality Systems**

106, Gupta Arcade, LSC, Mayur Vihar-I, Delhi, India Ph-22711940, 22711941, email: kvqa@satyam.net.in  
\*Subject to successful completion of surveillance audits