

Certificate of Registration



The following organization's quality management system has been assessed and registered by AMTAC Certification Services Limited as conforming to the requirements of:

ISO 13485:2003

Certificate Number
686 B

Initial Certification Date
13 June 2005

Certificate Issue Date
13 June 2011

Certificate Expiry Date
12 June 2014

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the accredited body.

AMTAC Certification Services Limited is owned by AMTAC Certification Services Holdings Limited, which is a wholly owned subsidiary of Intertek UK Holdings Limited.

AMTAC Certification Services Limited is an accredited body registered under UKAS with the identification number of 061.

In the issuance of this certificate, AMTAC assumes no liability to any party other than to the Client and then only in accordance with the agreed Terms and Conditions.

AMTAC Certification Services Limited
Davy Avenue
Knowlhill
Milton Keynes
MK5 8NL, UK
☎ Telephone
+44 (0)1908 857 750
Email: acsl@intertek.com

Organization:

GLOBAL ORTHOPAEDICS (UK) LIMITED

Unit 1 Applied House, Fitzherbert Spur, Farlington, Portsmouth
Hants, PO6 1TT

The Quality Management System is applicable to Design and manufacture of:

Sterile and non-sterile versions of implantable medical bone plates, implantable medical skeletal pins and wires, implantable medical bone screws and associated implantable nuts, washers and cerclage wire clips



0061

Authorised Signatory:

AMTAC Certification Services Limited, Milton Keynes, UK

This certificate is the property of AMTAC Certification Services Ltd

Certificate of Registration



The following organization's quality management system has been assessed and registered by AMTAC Certification Services Limited as conforming to the requirements of:

ISO 9001:2008

Certificate Number
686

Initial Certification Date
13 June 2005

Certificate Issue Date
13 June 2011

Certificate Expiry Date
12 June 2014

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Organization:

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Hants, PO6 1TT

The Quality Management System is applicable to Design and manufacture of:

Sterile and non-sterile versions of implantable medical bone plates, implantable medical skeletal pins and wires, implantable medical bone screws and associated implantable nuts, washers and cerclage wire clips



0061

Authorised Signatory:

AMTAC Certification Services Limited, Milton Keynes, UK

This certificate is the property of AMTAC Certification Services Ltd

Certificate Number
686 CE

Initial Certification Date
13 June 2005

Certificate Issue Date
02 August 2010

Certificate Expiry Date
12 June 2015

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

This Certificate is for the exclusive use of AMTAC's client and is provided pursuant to the agreement between AMTAC and its Client. AMTAC's responsibility and liability are limited to the terms and conditions of the agreement. AMTAC assumes no liability to any party, other than to the Client in accordance with the agreement, for any loss, expense or damage occasioned by the use of this Certificate. Only the Client is authorized to permit copying or distribution of this Certificate. Any use of the AMTAC name or one of its marks for the sale or advertisement of the tested material, product or service must first be approved in writing by AMTAC.

AMTAC Certification Services Limited is a Notified Body according to Directive 93/42/EEC for medical devices, with identification number 0473.

*AMTAC Certification Services Limited
Davy Avenue
Knowlhill
Milton Keynes
MK5 8N, UK
☎Telephone
+44 (0)1908 857 750
Email: acsl@intertek.com*

EC Certificate

FULL QUALITY ASSURANCE SYSTEM

Directive 93/42/EEC for Medical Devices, Annex II (3)

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0473 marking on those products listed below.

Organization:

GLOBAL ORTHOPAEDICS (UK) LIMITED

Unit 1 Applied House, Fitzherbert Spur, Farlington, Portsmouth
Hants, PO6 1TT

Sterile and non-sterile versions of:

Implantable medical bone plates
Implantable medical skeletal pins and wires
Implantable medical bone screws
Associated implantable nuts, washers and cerclage wire clips

Authorized Signatory



AMTAC Certification Services Limited, Milton Keynes, UK