



Certificate Number
623 A CE

Initial Certification Date
17 February 2004

Certificate Issue Date
24 February 2009

Certificate Expiry Date
16 February 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 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.

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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:

NiTi SURGICAL SOLUTIONS LTD

Administration, R&D, Engineering, Marketing and sales:
Yad Harutzim Street, Building 9E, Park Seeim, PO Box 8634,
Netanya, 42506, Israel

Production at:

4 Hatzoran Street, PO Box 8634, Sappir Business & Technology
Park, Netanya, 42506, Israel

**Intestinal compression anastomosis clips (CAC)
EndoCAR compression anastomosis ring**

Authorized Signatory

AMTAC Certification Services Limited, Milton Keynes, UK