



Certificate Number
069 C CE

Initial Certification Date
14 April 2010

Certificate Issue Date
03 February 2011

Certificate Expiry Date
13 April 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 8NL, 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 (OBL)

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 of the Directive 93/42/EEC on medical devices via an Own Branding arrangement. We certify that the full quality system conforms with the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0473 marking on those products listed below.

Organization:

HANITA LENSES

Kibbutz Hanita, 22885, Israel

Injector for foldable lenses:

SoftJect 2.4-1P Foldable Intra Ocular Lens Delivery System

SoftJect 1.8-1P Foldable Intra Ocular Lens Delivery System

Authorized Signatory:

AMTAC Certification Services Limited, Milton Keynes, UK