

EC Certificate

FULL QUALITY ASSURANCE SYSTEM
Directive 93/42/EEC for Medical Devices, Annex II (3)

Certificate Number
570 CE

Initial Certification Date
13 January 2003

Certificate Issue Date
31 October 2007

Certificate Expiry Date
12 January 2013

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.

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:

ORIGEN BIOMEDICAL INC

4020 S. Industrial 160, Austin, Texas 78744, USA

Bags for cell culture, freezing bags and vascular catheters
Wrist fixators
Cryopreservation solutions

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



Authorized Signatory