

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No.**CE 640754**

Issued To:

**ASTROLABE - Fabricação de Implantes
Médicos, Lda
Rua José Gomes Ferreira
No 2 Armazém 1
São Julião do Tojal- Loures
2660-517
Portugal**

In respect of:

**The design and manufacture of sterile and non-sterile metallic bone plates, metallic bone screws, Kirschner wires, metallic bone staples, and metallic washers for use in upper and lower extremities and limbs, and instruments connected to an active device.
The aspects of Annex II related to the conformity of Class I Measuring instruments with the metrological requirements.**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.