

EC Certificate - Full Quality Assurance System

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

No. CE 85507
Issued To: **Arthrex, Inc.**
1370 Creekside Boulevard
Naples
Florida
34108-1945
USA

In respect of:

See certificate scope page.

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

First Issued: 2004-06-18

Date: 2019-06-17

Expiry Date: 2024-05-26

...making excellence a habit.™

Page 1 of 2

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.

Certificate No: CE 85507

Certificate Scope:

The design, development and manufacture of metallic, non-metallic and bioabsorbable implants, suture, total joint replacement devices and associated trials and instrumentation, partial joint resurfacing devices, arthroscopic and minimally invasive surgical instruments, cannula, electromechanical/electrosurgical ablation, cutting and fluid management devices, blood cell separators, centrifuges, and sterile disposable processing sets.

Those aspects of Annex II related to securing and maintaining sterility in the manufacture of noninvasive traction devices, drape sets, cushions and limb positioners, backflow caps, marking pens, syringes, and retractors, and related to the accuracy of metrology in the manufacture of general surgical devices with measuring functions.

First Issued: **2004-06-18**

Date: **2019-06-17**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 2 of 2

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.