

# EC Certificate - Full Quality Assurance System

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

**No.** CE 661971  
**Issued To:** **Active Life Scientific, Inc.**  
**1027 Garden Street**  
**Santa Barbara**  
**California**  
**93101**  
**USA**

In respect of:

**Design, development, and manufacturing of OsteoProbe for diagnosing and monitoring material aspects of bone quality.**

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: **2017-08-15**

Date: **2020-04-06**

Expiry Date: **2022-08-14**

...making excellence a habit.™

Page 1 of 1

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.

# EC Certificate - Full Quality Assurance System

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

## List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 661971**  
Date: **2020-04-06**  
Issued To: **Active Life Scientific, Inc.**  
**1027 Garden Street**  
**Santa Barbara**  
**California**  
**93101**  
**USA**

**Subcontractor:**

**Service(s) supplied**

Emergo Europe  
Prinsessegracht 20  
2514 AP The Hague  
The Netherlands

**EU Representative**

...making excellence a habit.™

# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 661971**  
 Date: **2020-04-06**  
 Issued To: **Active Life Scientific, Inc.**  
**1027 Garden Street**  
**Santa Barbara**  
**California**  
**93101**  
**USA**

Date	Reference Number	Action
15 August 2017	8608289	First Issue.
04 July 2018	8867958	Amendment to address from: 27 E Cota Street Suite 503 to 27 E Cota Street Suite 400.
27 February 2019	8814865	Traceable to NB 0086.
Current	3065337	Updated the manufacturer's address from Suite 400, 27 E Cota Street, Santa Barbara, California 93101, USA to 1027 Garden Street, Santa Barbara, California, 93101, USA

...making excellence a habit.™

Page 1 of 1

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.