UKCA Certificate - Full Quality Assurance System

Part II of The Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

No. **UKCA 764934**

Issued To: **Active Life Scientific, Inc.**
1027 Garden Street
Santa Barbara
California
93101
USA

In respect of:

Design, manufacture and final inspection 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 Part II of the Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part II of Schedule 2A to The Medical Devices Regulations 2002]. The quality assurance system meets the requirements of the regulation. For the placing on the market of class III products an Annex II (modified as described above) Section 4 certificate is required.

For and on behalf of BSI, an Approved Body for the above Regulation (Approved Body Number 0086):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2022-08-10** Date: **2022-08-10** Expiry Date: **2027-08-09**

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Supplementary Information to UKCA 764934

Issued To:

Active Life Scientific, Inc.
1027 Garden Street
Santa Barbara
California
93101
USA

Device Code	Device Name	Intended purpose per IFU
Class IIa		
MD 1301	OsteoProbe (with end user sterilised tip assembly)	---

First Issued: **2022-08-10** Date: **2022-08-10** Expiry Date: **2027-08-09**

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Part II of The Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

Certificate No:	**UKCA 764934**
Date:	**2022-08-10**
Issued To:	**Active Life Scientific, Inc.** **1027 Garden Street** **Santa Barbara** **California** **93101** **USA**

Subcontractor:	**Service(s) supplied**
MedEnvoy UK Limited 85 Great Portland Street, First Floor London W1W 7LT United Kingdom	**UK Responsible Person**

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UKCA Certificate - Full Quality Assurance System Certificate History

Certificate No: **UKCA 764934**
Date: **2022-08-10**
Issued To: **Active Life Scientific, Inc.**
1027 Garden Street
Santa Barbara
California
93101
USA

Date	Reference Number	Action
Current	3615625 3734166	First Issue; Traceable to CE 661971. Renewal

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