

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]

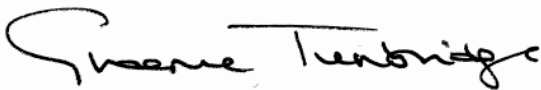
No. UKCA 764934
Issued To: Active Life Scientific, Inc.
1027 Garden Street
Santa Barbara
California
93101
USA

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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Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the regulation as demonstrated through the required surveillance activities of the Approved Body.

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

Approved Body Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, UK. Tel: + 44 845 080 9000

Corporate Contact: BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London, W4 4AL, UK.

A member of BSI Group of Companies.

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Supplementary Information to UKCA 764934

Issued To:

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

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List of Critical Subcontractors and Crucial Suppliers

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

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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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Certificate History

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Date: **2022-08-10**
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Date	Reference Number	Action
Current	3615625 3734166	First Issue; Traceable to CE 661971. Renewal

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