

EC Certificate - Full Quality Assurance System

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

No. CE 665106
Issued To: Straxcorp Pty Ltd
Suite 5, Level 10
470 Collins Street
Melbourne
Victoria
3000
Australia

In respect of:

Design and manufacture of software applications for the analysis of human bone health.

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: **2017-01-04**

Date: **2020-10-28**

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

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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.

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Supplementary Information to CE 665106

Issued To:

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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 1111	Software using data from computed tomography scans of the Distal Radius to produce analysis report on the bone microarchitecture and its fragility.	N/A

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

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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List of Significant Subcontractors

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

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Melbourne
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Subcontractor:

Service(s) supplied

Advena Ltd
Tower Business Centre
2nd Floor
Tower Street
Swatar, BKR 4013
Malta

EU Representative

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 665106**
 Date: **2020-10-28**
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 Melbourne
 Victoria
 3000
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Date	Reference Number	Action
04 January 2017	8648763	First issue. Transfer from another Notified Body.
06 February 2019	8898240	Traceable to NB 0086.
Current	3313793	Renewal, added Class IIa device table, and changed EU Representative Advena Ltd's address from Pure Offices, Plato close, Warwickshire, CV34 6 WE United Kingdom to Tower Business Centre, 2nd Flr. Tower Street, Swatar, BKR 4013 Malta

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