

EC Certificate - Full Quality Assurance System

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

No. **CE 684095**
Issued To: **Springlife Medical B.V.**
Kaap de Goede Hooplaan 7
3526 AR Utrecht
The Netherlands

In respect of:

Design and manufacture of transcutaneous and invasive Pulsed Radiofrequency device for pain relief.

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: **2020-02-18**

Date: **2020-02-18**

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

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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 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.

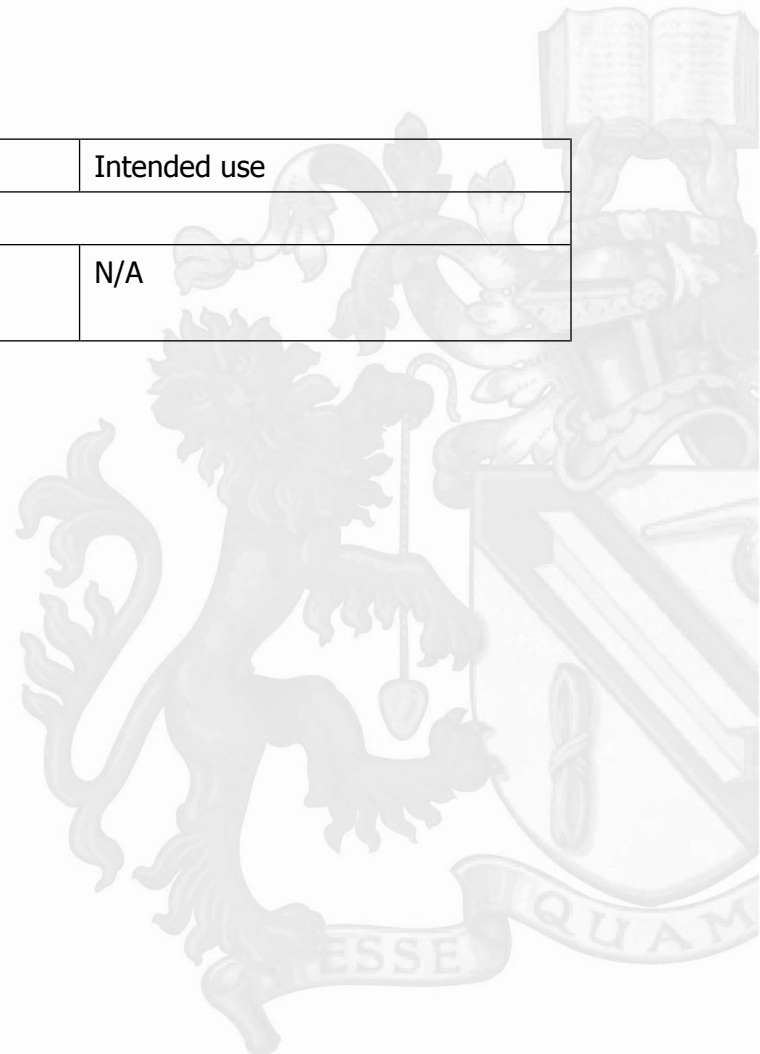
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Supplementary Information to CE 684095

Issued To:

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NBOG Code(s)	Device Description	Intended use
Class IIa		
MD 1103 MDS 7010	Pulsed radiofrequency stimulator for pain relief.	N/A



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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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3526 AR Utrecht
The Netherlands

Subcontractor:

Service(s) supplied

Unitron Group B.V.
Schansestraat 7
4515 RN IJzendijke
The Netherlands

Manufacture

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Certificate History

Certificate No: **CE 684095**
 Date: **2020-02-18**
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Date	Reference Number	Action
Current	8857876	First issue.

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