By Royal Charter

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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Supplementary Information to CE 684095

Issued To:

Springlife Medical B.V.
Kaap de Goede Hooplaan 7
3526 AR Utrecht
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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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List of Significant Subcontractors

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

Certificate No:	**CE 684095**
Date:	**2020-02-18**
Issued To:	**Springlife Medical B.V.** **Kaap de Goede Hooplaan 7** **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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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 684095**
Date: **2020-02-18**
Issued To: **Springlife Medical B.V.**
Kaap de Goede Hooplaan 7
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The Netherlands

Date	Reference Number	Action
Current	8857876	First issue.

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