By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 651490**

Issued To: **Micropace Pty Ltd**
41/159 Arthur Street
Homebush West
New South Wales
2140
Australia

In respect of:

Design and manufacture of Cardiac Stimulators for diagnostic electrical stimulation of the heart for initiation and termination of tachyarrhythmias, refractory measurements and measurements of electrical conduction.

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: **2016-04-27** Date: **2020-03-04** Expiry Date: **2024-05-26**

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Supplementary Information to CE 651490

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Class IIb		
GMDN	**Device or Generic Device Group**	**Intended purpose as per IFU**
35976	Stimulator, electrical, cardiac, diagnostic	The Micropace Cardiac Stimulator is intended to be used for diagnostic electrical stimulation of the heart for the purpose of initiation and termination of tachyarrhythmias, refractory measurements and measurements of electrical conduction.

First Issued: **2016-04-27** Date: **2020-03-04** Expiry Date: **2024-05-26**

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List of Significant Subcontractors

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

Certificate No:	**CE 651490**
Date:	**2020-03-04**
Issued To:	**Micropace Pty Ltd** **41/159 Arthur Street** **Homebush West** **New South Wales** **2140** **Australia**

Subcontractor:	**Service(s) supplied**
Advena Ltd Tower Business Center 2nd Floor, Tower Street Swatar BKR 4013 Malta	**EU Representative**
Micropace EP Inc., 3205 West Warner Avenue Santa Ana California 92704 USA	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 651490**

Date: **2020-03-04**

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Date	Reference Number	Action
27 April 2016	8501818	Initial Issue. Transferred from another Notified Body.
09 June 2017	8676990	Change of manufacturer address from "Unit 7, 186-188 Canterbury Road, Canterbury, New South Wales, 2193, Australia" to 41/159 Arthur Street, Homebush West, New South Wales, 2140, Australia"
12 February 2019	8764551	Traceable to NB 0086.
28 March 2019	9717553	Certificate re-issue to change EU representative address from United Kingdom to Malta.
Current	9733043	Certificate renewal. Addition of product table.