bsi.

By Royal Charter

EC Certificate - Full Quality Assurance

Directive 90/385/EEC on Active Implantable Medical Devices, Annex 2, excluding Section 4

No. **CE 89729**

Issued To: **SynCardia Systems, Inc**
1992 East Silverlake Road
Tucson
Arizona
85713
USA

In respect of:

The design and manufacture of temporary Total Artificial Heart and External Drivers

on the basis of our examination of the quality assurance system under the requirements of Council Directive 90/385/EEC, Annex 2, excluding Section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of devices covered by this certificate an EC design-examination certificate according to 90/385/EEC, Annex 2, section 4 is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **16 May 2005** Date: **19 May 2015** Expiry Date: **15 May 2020**

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EC Certificate - Full Quality Assurance

Directive 90/385/EEC on Active Implantable Medical Devices, Annex 2, excluding Section 4

List of Significant Subcontractors

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

Certificate No:	**CE 89729**
Date:	**19 May 2015**
Issued To:	**SynCardia Systems, Inc** **1992 East Silverlake Road** **Tucson** **Arizona** **85713** **USA**

Subcontractor:	**Service(s) supplied**
Electrochem Solutions 13955 SW Milikan Way Beaverton Oregon 97005 USA	**Crucial Supplier**
Emergo Europe Molenstraat 15 2513 BH The Hague Netherlands	**EU Representative**
Nelson Laboratories, Inc. 6280 S. Redwood Rd. Salt Lake City Utah 84123 USA	**Crucial Supplier**

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List of Significant Subcontractors

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Certificate No:	**CE 89729**
Date:	**19 May 2015**
Issued To:	**SynCardia Systems, Inc** **1992 East Silverlake Road** **Tucson** **Arizona** **85713** **USA**

Subcontractor:	**Service(s) supplied**
Proven Process Medical Devices Inc. 110 Forbes Boulevard Mansfield Massachusetts 02048 USA	**Manufacture**
Sterigenics 5725 West Harold Gatty Drive Salt Lake City Utah 84116 USA	**Sterilization**
SynCardia Systems, Inc. 1978 East Silverlake Road Tucson Arizona 85713 USA	**Manufacture**

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Directive 90/385/EEC on Active Implantable Medical Devices, Annex 2, excluding Section 4

List of Significant Subcontractors

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Certificate No:	**CE 89729**
Date:	**19 May 2015**
Issued To:	**SynCardia Systems, Inc** **1992 East Silverlake Road** **Tucson** **Arizona** **85713** **USA**

Subcontractor:	**Service(s) supplied**
SynCardia Systems, Inc 1974 East Silverlake Road, Suite 100, Tuscon Arizona 85713 USA	**Manufacture**

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EC Certificate - Full Quality Assurance Certificate History

Certificate No: **CE 89729**

Date: **19 May 2015**

Issued To: **SynCardia Systems, Inc**
1992 East Silverlake Road
Tucson
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USA

Date	Reference Number	Action
16 May 2005		First Issue
18 April 2006		Minor address change "from Avenue to Road". This change was implemented by the client's local authorities
07 March 2007		Change to scope - addition of "temporary"; addition of 1986 East Silverlake Road facility; addition of Berlin Heart AG as a significant sub-contractor
13 October 2009	7443921	Addition to the list of significant subcontractors with Proven Process Medical Devices, Inc for Manufacturing and Medical Device Consultants International Ltd as the EU Representative
30 April 2010	7510506	Certificate Renewal
10 December 2010	7611630	Removed Medical Device Consultants as the EU Representative and replaced with Emerge, The Hague, as new EU Representative.

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EC Certificate - Full Quality Assurance Certificate History

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Date	Reference Number	Action
30 April 2012	7816624	Extension of scope to include SPUS polymer manufacture Hospital cart and driver caddy assembly brought in-house using same components and assembly methods as used by former sub-contractor (Proven Process)
19 May 2015	8333041	Certificate renewal. Nelson Laboratories changed from significant subcontractor to crucial supplier. Electrochem Solutions added as crucial supplier.