

# Certificate

## Design Examination

No. CE 93783



Issued to:

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

In respect of:

**SynCardia temporary Total Artificial Heart (TAH-t) and external drivers**

on the basis of our examination under the requirements of Council Directive 90/385/EEC, Annex 2, Section 4.

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

A handwritten signature in black ink, appearing to be 'D. Ford', written over a horizontal line.

David Ford, Director, Healthcare and Testing Services

First Issued: 16 May 2005

Date: 25 May 2010

Expiration Date: 15 May 2015

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**Conditions of Approval**

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive.

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## Supplementary Information to CE 93783

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**Product:** SynCardia temporary Total Artificial Heart (TAH-t) and external drivers

Product Description	Product code
temporary Total Artificial Heart (TAH-t)	500101
Circulatory Support System (CSS)	400207-XXX
Surgical Spares Kit (SSK)	500177
EXCOR TAH-t Portable Pneumatic Driver	FE-D01E-002x01
Companion Driver System	C-500001
Companion Drive Unit	C-400001
Companion Hospital Cart	C-400002
Companion Driver Caddy	C-400003
Freedom Driver	595000-001
Freedom Driver System Discharge Kit - EU	595631-001
Freedom Driver System Bags	495100-001

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### History of Certificate

Date	Reference Number	Action
16 May 2005	10065896	First issue
18 April 2006	10078302	Minor address change "from Avenue to Road". This change was implemented by the client's local authorities
17 July 2006	10080454	The addition of EXCOR TAH-t Portable Pneumatic Driver incorporating Syncardia Version 3.1 application software and EXCOR Firmware Version 9.4, provided as an alternative to CSS
07 March 2007	10082583	Minor design changes including the modification of the accompanying documents; and firmware to Version 9.4.1
13 October 2009	10102209	The addition of Companion Driver System and related accessories.
01 March 2010	10108615	The addition of Freedom Driver System and related accessories. Removal of reference to Cardiowest from scope.
25 May 2010	10116223	Certificate renewal

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