

EC Design-Examination Certificate

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

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

BSI has performed a design examination on the above devices in accordance with the Council Directive 90/385/EEC, Annex 2 Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex 2 excluding Section 4 certificate 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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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 certificate was issued electronically and is bound by the conditions of the contract.

EC Design-Examination Certificate

Supplementary Information to CE 93783

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SynCardia Systems, Inc
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Product: SynCardia temporary Total Artificial Heart (TAH-t) and external drivers

Product Description	Product code
70cc temporary Total Artificial Heart (TAH-t)	500101
Surgical Spares Kit (SSK) for 70cc TAH-t	500177
Companion 2 Driver System	397002-001
Companion Hospital Cart	C-400002 397003-001
Companion Driver Caddy	C-400003 397001-001
Freedom Driver	595000-001
Freedom Driver System Discharge Kit - EU	595631-001
Freedom Driver System Bags	495100-001
Freedom Battery Charger	395103
Freedom Standby Kit	595510-001
SynCardia Hand Pump	397004-001
Companion Drive lines	C-400008-001 193002-001
Freedom Onboard Battery	295025-001

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

Product Description	Product code
Companion External Battery	C-400009 293001-001
50cc temporary Total Artificial Heart (TAH-t)	570500-001
Surgical Spares Kit for the 50cc TAH-t	550177-001

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Certificate History

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 Cardiwest from scope.
25 May 2010	10116223	Certificate renewal

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Date	Reference Number	Action
14 January 2011	10117000	Change to Freedom Driver System – update of software to v1.13, service life extension, addition of standby kit and addition of battery charger.
25 July 2011	10123788	The addition of Companion 2 Driver System and SynCardia Hand Pump. Change of indications for Companion Driver to in-hospital use only. Removal of EXCOR Portable Pneumatic Driver. Companion update to software from V1.26 to V1.37. Companion Hospital Cart – removal of locking mechanism.
06 September 2011	10129964	Freedom Firmware Update from V1.13 to V1.14. Reduction in audible alarm volume.

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Date	Reference Number	Action
06 January 2012	10131627	Companion 2 software update to update the Graphical User Interface (GUI) software to: v1.0.2160. This submission also included 2 changes to the Companion 2 Operator Manual: 1. Change to the External Air Pressure Operating Range: 50 – 80 PSI (3.5 – 5.5 Bar) 2. Operator Manual Section 8 Update clarification of the transition from Single Pulse Mode to standard beat rates.
22 February 2012	10133855	Companion 2 firmware update to v1.25 (fill volume algorithm update)
10 September 2012	10136260	Addition of P/N 550101 TAH-t with Medtronic OP valves
24 July 2013	10142563	Addition of part numbers for Companion Hospital Cart 397003-001 and Companion Driver Caddy 397001-001. Removal of part numbers for temporary Total Artificial Heart (TAH-t) with Medtronic OP Valves 550101 and Circulatory Support System (CSS) Console 400207-XXX.

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Date	Reference Number	Action
16 September 2013	10143111	Three minor amendments to the Freedom Driver System: 1. Manufacturing transfer of Freedom Plastics and replacement of EMI coating. 2. Extension of the Freedom Onboard Battery Use By Date. 3. Freedom Power Adaptor retention clip repair. One minor amendment to the Companion 2 Driver System: 1. Extension of the Companion External Battery Use By Date. Addition of unlisted, but previously approved component.
12 November 2013	10143846	Addendum – Transfer of manufacturing of External Companion Battery from Dow Kokam to Electrochem. Change of cells from Dow Kokam flat cells to Panasonic/Sanyo-type cylindrical cells.
12 November 2013	10143847	Addendum – Transfer of manufacturing of Companion 2 Internal Battery from Dow Kokam to Electrochem. Change to assembly process to improve manufacturability.

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Date	Reference Number	Action
12 March 2014	10137704	Addendum - evidence of compliance with 3rd Edition of EN 60601-1 for the Companion 2 Driver System and Freedom Driver System. Remove Companion Driver System and Companion Drive Unit from Certificate. Revise Companion Hospital Cart part number to 397003-001 and add Companion Driver Caddy part number 397001-001.
17 April 2014	10145347	Addendum – Change of valves used in TAH-t from Medtronic Hall valve to Syncardia Hall valve. Minor update to IFU to remove reference to Medtronic.
17 July 2014	10149406	Change to amend error in description for 500101
24 December 2014	10151707	Addendum - Addition of the 50cc TAH-t and Surgical Spares Kit for the 50cc TAH-t. Update to add 70cc to the existing TAH-t and Surgical Spares kit.
04 March 2015	10150194	Addendum – Change to components of the pressure sensor board in the Companion 2 and the addition of an alternate supplier for the board.

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Certificate History

Date	Reference Number	Action
19 May 2015	10155566	Certificate Renewal



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