

# EC Design-Examination Certificate

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

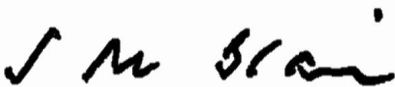
**No.** CE 665479  
Issued To: **SynCardia Systems, LLC**  
**1992 East Silverlake Road**  
**Tucson**  
**Arizona**  
**85713**  
**USA**

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):



Stewart Brain, Head of Compliance & Risk -  
Medical Devices

First Issued: **2017-01-10**

Date: **2017-05-26**

Expiry Date: **2020-05-15**

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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 665479

Issued To:

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

**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-40009 293001-001
50cc temporary Total Artificial Heart (TAH-t)	570500-001
Surgical Spares Kit for the 50cc TAH-t	550177-001
Companion 2 Air Hose Assembly (EU Configuration)	297037-002
Companion 2 Air Hose Assembly (FR Configuration)	297037-004

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## Certificate History

Date	Reference Number	Action
10 January 2017	10165082	First issue. Transfer from CE 93783. New legal manufacture name from SynCardia Systems, Inc. To SynCardia Systems, LLC.
	10162969	Change to the Freedom Driver Main PCBA from dry pressure sensors to liquid compatible pressure sensors. Addition of MJS Designs as Freedom Driver Main PCBA supplier.
26 May 2017	10171629	Amendment - Addition of Murrietta Circuits as sole supplier of Freedom Main PCBA and removal of MJS Designs as SynCardia supplier. Change of Authorized Representative address.
	10169268	Amendment - Approval of 297037-004 French configuration air hose - Conductive hose terminated with Swagelok quick connect valve and terminated at the source end, with an AFNOR compliant medical air connector. Update certificate with previously approved EU configuration air hose, 97037-002.

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