



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485: 2003

This is to certify that:

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

Holds Certificate No:

FM 88700

and operates a Quality Management System which complies with the requirements of ISO 13485: 2003 for the following scope:

Design, manufacture, and distribution of temporary Total Artificial Heart. Design, manufacture, distribution and service of external drivers. Manufacture of Segmented Polyurethane Solution (SPUS).

This includes Quality System processes at:

1986 East Silverlake Road, Tucson AZ 85713
1974 East Silverlake Road, Tucson AZ 85713
1978 East Silverlake Road, Tucson AZ 85713

For and on behalf of BSI:

VP Regulatory Affairs, BSI Group America Inc.

Originally registered: 11/27/2004

Effective Date: 12/10/2013

Expiry Date: 12/09/2016



CMDCAS
Recognized
Registrar



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...making excellence a habit.™

This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](http://www.bsigroup.com/ClientDirectory). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12110 Sunset Hills Road, Suite 200, Reston, VA 20190, USA
A Member of the BSI Group of Companies.