

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

DesignPlex Biomedical LLC
3425 Clayton Road East
Fort Worth
Texas
76116
USA

Holds Certificate Number:

MD 724622

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Contract services for design, development and manufacturing of medical devices including active implantable medical devices for mechanical, electronic and related software for use in the cardiovascular system.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2021-02-25

Latest Revision Date: 2024-02-21

Effective Date: 2024-02-25

Expiry Date: 2027-02-24

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