

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Cirtec Medical Corporation

99 Print Shop Road
Enfield
Connecticut
06082
USA

Holds Certificate Number:

FM 85801

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

Contract design and development, manufacturing and clean room packaging of surgical instruments and active implantable medical devices. Processing services include laser welding and laser marking, hermetic sealing and hermetic verification, and ethylene oxide sterilization.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2004-07-21

Latest Revision Date: 2023-02-21

Effective Date: 2023-04-11

Expiry Date: 2026-04-10

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