



Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2016

The National Standards Authority of Ireland certifies that:
Greatbatch Medical
10000 Wehrle Drive
Clarence, NY 14031
USA

has been assessed and deemed to comply with the
requirements of the above standard in respect of the scope of
operations given below:

The Design, Manufacture and Test of Capacitors and Lithium Batteries, Lithium-Ion Rechargeable Batteries, Feedthroughs, Filter Feedthroughs, Shield Assemblies, Coated Components, Ceramics and Machined components for Use in Implantable and Non-Implantable Medical Devices.

Additional sites covered under this multi-site certification are listed on the Annex (File No. MD19.8039)

Approved by:
Pamela Burdette Miller
Certification Manager

Registration Number: MD19.8039
Certification Granted: August 23, 2016
Effective Date: August 21, 2026
Expiry Date: August 22, 2028



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National Standards Authority of Ireland, 20 Trafalgar Square, Nashua, New Hampshire, NH 03063, USA T +1 603 882 4412



Annex to Certificate Number: MD19.8039

Scope of Registration:

The Design, Manufacture and Test of Capacitors and Lithium Batteries, Lithium-Ion Rechargeable Batteries, Feedthroughs, Filter Feedthroughs, Shield Assemblies, Coated Components, Ceramics and Machined components for Use in Implantable and Non-Implantable Medical Devices.

Activity

Location

The Design, Manufacture and Test of Feedthroughs, Filter Feedthroughs and Shield Assemblies for Use in Implantable and Non-Implantable Medical Devices.

Design of Capacitors, lithium batteries and lithium-ion rechargeable batteries for use in implantable and non-implantable medical devices.

Test of Batteries and Lithium-ion rechargeable batteries for use in implantable and non-implantable medical devices.

Manufacture of coated components, ceramics and machined components for use in implantable and non-implantable medical devices.

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File No.: MD19.8039

The Manufacture and Test of Capacitors, Lithium Batteries and Lithium-ion Rechargeable Batteries for use in Implantable and Non-implantable Medical Devices.

Greatbatch Medical
11900 Walden Avenue
Alden, NY 14004
USA
File No.: MD19.8039/A

**Verified by:
Certification Manager**