



NSAI

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, and Ceramics 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:
Geraldine Larkin
Chief Executive Officer

Approved by:
Susan Murphy
European Medical Device
Operations Manager

Registration Number: MD19.8039
Certification Granted: August 23, 2016
Effective Date: October 23, 2018
Expiry Date: August 22, 2019



National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800



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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, and Ceramics for Use in Implantable and Non-Implantable Medical Devices

Activity

Location

Administration (HQ), Design,
Manufacturing, Test

Greatbatch Medical
10000 Wehrle Drive
Clarence, NY 14031
USA
File No.: MD19.8039

Design, Manufacturing, Test

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

Verified by:
Operations Manager