



# 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:

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**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:  
Kevin Mullaney  
Director of Certification

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Registration Number: MD19.8039  
Certification Granted: August 23, 2016  
Effective Date: August 23, 2022  
Expiry Date: August 22, 2025





## **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:**  
**Director of Certification**