

Certificate of Registration of Quality Management System to ISO 13485:2016

The National Standards Authority of Ireland certifies that:

Greatbatch Medical

2300 Berkshire Lane North

Minneapolis, MN 55441

USA

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

Design and Development, Manufacture, Contract Manufacture, and Distribution of Active Implantable Medical Devices, Implantable Leads for AIMDs and Related Accessories, Percutaneous Introducer Systems, Intravascular Catheters, Delivery Sheaths, Safety Needles and Components.

Approved by: Geraldine Larkin Chief Executive Officer Approved by: Caroline Dore Geraghty Director of Medical Devices / Head of Notified Body

Registration Number: CM19.4895 Certification Granted: December 11, 2018 Effective Date: December 11, 2018

Expiry Date: December 10, 2021



