



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, S. de R.L. de C.V.
Boulevard Héctor Terán Terán #20120
Ciudad Industrial
Tijuana, Baja California, 22444
Mexico

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

The Manufacture, Assembly and Testing of Components and Sub-Assemblies for Implantable Medical Devices and other Medical Applications including Feedthroughs and Filtered Feedthroughs and the Manufacture of non sterile, Acetabular Reamer orthopedic instruments and the Manufacture of Sterile and Non-Sterile Introducer, Catheter and Components.

Approved by:
Geraldine Larkin
Chief Executive Officer

Approved by:
Caroline Dore Geraghty
Director of Medical Devices
/ Head of Notified Body

Registration Number: MD19.4211
Certification Granted: December 04, 2006
Effective Date: January 19, 2019
Expiry Date: January 18, 2022



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