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

Australia-Therapeutic Goods (Medical Devices) Regulations, 2002,
☒ Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure.
Brazil- RDC ANVISA n. 16/2013 RDC ANVISA n. 23/2012 RDC ANVISA n. 67/2009
Canada- Medical Devices Regulations – Part 1- SOR 98/282
Japan- MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act (,as applicable)
United States- 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D
☒ 21 CFR 820 – Quality System Regulation

The National Standards Authority of Ireland is an MDSAP Recognized Auditing Organization and certifies that:

Greatbatch Medical
2300 Berkshire Lane North
Minneapolis, MN 55441
USA
D-U-N-S: 1787446320

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

Design and Development, Manufacture, and Distribution of Active Implantable Medical Devices, Implantable Leads for AIMDs, Percutaneous Introducer Kits, Intravascular Catheters and Delivery Sheaths.

Approved by:
Geraldine Larkin
Chief Executive Officer

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

Certificate Number: MP19.4895 /Rev 1
Certification Granted: 2018/12/11
Effective Date: 2018/12/11
Expiry Date: 2021/12/10

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All valid certifications are listed on NSAI's website – www.nsaiinc.com
The continued validity of this certificate may be verified under "Approved Client Listing