



America

# CERTIFICATE

No. QS6 041921 0033 Rev. 03

**Certificate Holder:**

**Medtronic Xomed, Inc.**  
6743 Southpoint Drive North  
Jacksonville FL 32216  
USA

**Certification Mark:****Scope of Certificate:****See Page 2 for Overall Scope Statement.****Standard(s):****ISO 13485:2016****Regulatory Authority(ies):**

**Australia TGA, Brazil ANVISA, Health Canada, USA FDA,  
MHLW / PMDA. See attached for listing of specific  
regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website [www.tuvsud.com/ps-cert](http://www.tuvsud.com/ps-cert)

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

**REPs Facility ID:****F001282****Effective Date:****2022-10-19****Expiry Date:****2025-03-06**

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**Date of Issue:** 2022-11-10

( Renee Walker )  
Manager, US Certification Body,  
Medical and Health Services

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## Regulatory Requirements: Audit/Certification Criteria

### 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 Device Regulations – Part 1- SOR 98/282

### Japan

- MHLW Ministerial Ordinance 169, Article 4 to Article 68  
- PMD Act

### United States

- 21 CFR Part 803  
- 21 CFR Part 806  
- 21 CFR Part 807 – Subparts A to D  
- 21 CFR Part 820

## Overall Scope Statement:

**Design and Development, Manufacture, Distribution, Installation, and Service of Non-Active Implants (Tympanostomy Ventilation Tubes, Ossicular Reconstruction Implants, Snoring and OSA Implants, Silicone Strips and Sheets, Otologic Lamina Packing); Active Medical Devices (Power System Consoles, Drills, Handpieces, Blades, Burs, Nerve Monitoring Systems, Probes, Electrodes, EMG Tubes, Nerve Stimulators, Injection Monitor, Low Pressure Pulse Generator, Endoscope Systems / Sheaths), Bone Conduction Hearing Systems); and Non-Active Medical Devices (Manual Surgical Instruments, Disposable Surgical Instruments, ENT Packing, Wipes, Headbands, Neurosurgical Paddies and Strips, Endotracheal Tubes, OBGYN Packing including Medical Sponges, Dressings and Accessories, Sponges for Precision Cleaning and Sponge Components for OEM Use, Irrigation / Cleaning Solutions, Sheaths) for use in Otolaryngology, Rhinology, Sinus Endoscopy, Laryngology, Ophthalmology, Neurology, Aesthetic Plastic Surgery, Obstetrics and Gynecology, Orthopedic, General Surgery and Servicing of Active Medical Devices**

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**Facility(ies):**

Medtronic Xomed, Inc.  
6743 Southpoint Drive North, Jacksonville FL 32216, USA

Medtronic Xomed, Inc.  
950 Flanders Road, Mystic CT 06355, USA

**Facility Scopes:**

**Medtronic Xomed, Inc.**  
6743 Southpoint Drive North, Jacksonville FL 32216, USA

Design and Development, Manufacture, Distribution, Installation, and Service of Non-Active Implants (Tympanostomy Ventilation Tubes, Ossicular Reconstruction Implants, Snoring and OSA Implants, Silicone Strips and Sheets, Otologic Lamina Packing); Active Medical Devices (Power System Consoles, Drills, Handpieces, Blades, Burs, Nerve Monitoring Systems, Probes, Electrodes, EMG Tubes, Nerve Stimulators, Injection Monitor, Low Pressure Pulse Generator, Endoscope Systems / Sheaths), Bone Conduction Hearing Systems); and Non-Active Medical Devices (Manual Surgical Instruments, Disposable Surgical Instruments, ENT Packing, Wipes, Headbands, Neurosurgical Paddies and Strips, Endotracheal Tubes, OBGYN Packing including Medical Sponges, Dressings and Accessories, Sponges for Precision Cleaning and Sponge Components for OEM Use, Irrigation / Cleaning Solutions, Sheaths) for use in Otology, Rhinology, Sinus Endoscopy, Laryngology, Ophthalmology, Neurology, Aesthetic Plastic Surgery, Obstetrics and Gynecology, Orthopedic, General Surgery and Servicing of Active Medical Devices  
REPs Facility ID: F001282

**Medtronic Xomed, Inc.**  
950 Flanders Road, Mystic CT 06355, USA

Design and Development, Manufacture, Distribution, Installation, and Service of Non-Active Medical Devices (ENT Packing, Wipes, Headbands, Neurosurgical Paddies and Strips, OBGYN Packing, including Medical Sponges, Dressings and Accessories, Sponges for Precision Cleaning and Sponge Components) for ORM Medical Use, and Irrigation / Cleaning Solutions  
REPs Facility ID: F002196

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