# State of Minnesota - Secretary of State

This Certificate is not valid for use anywhere within the United States of America, its territories or possessions.

## Apostille

(Convention de La Haye du 5 Octobre 1961)

1. **Country** (Pays)**: United States of America**
   **This public document** (Le présent acte public) **Certificate**

2. **has been signed by** (a été signé par) **Cindi A. Bigelbach**

3. **acting in the capacity of** (agissant en qualité de) **Notary Public, State of Minnesota**

4. **bears the seal / stamp of** (est revêtu du sceau / timbre de)
   **Cindi A. Bigelbach, Notary Public, State of Minnesota**

## Certified
## Attesté

5. **at** (á) **St. Paul, Minnesota**

6. **Date** (Date) **04/16/2019**

7. **by** (par) **Secretary of State, State of Minnesota**

8. **File No** (Sous nº) **1081026900064**

9. **Seal / Stamp** (Sceau / Timbre)**:**

10. **Signature** (Signature)**:**

Steve Simon
Secretary of State
State of Minnesota

This Apostille only certifies the authenticity of the signature and the capacity of the person who has signed the public document, and, where appropriate, the identity of the seal or stamp which the public document bears.
This Apostille does not certify the content of the document for which it was issued.
To verify the issuance of this Apostille, see **https://apostille.sos.state.mn.us**.
**This certificate does not constitute an Apostille under the Hague Convention of 5 October 1961, when it is presented in a country which is not a party to the convention. In such cases, the certificate should be presented to the consular section of the mission representing that country.**

Cette Apostille atteste uniquement la véracité de la signature, la qualité en laquelle le signataire del'acte a agi et, le cas échéant, l'identité du sceau ou timbre don't cet acte public est revêtu.
Cette Apostille ne certifie pas le contenu de l'acte pour lequel elle a été émise.
Cette Apostille peut étre vérifiée à l'adresse suivante:**https://apostille.sos.state.mn.us**. **Ce certificat ne constitue pas une Apostille en vertu de la Convention de La Haye du 5 Octobre 1961, lorsque présenté dans un pays qui n'est pas partie à cette Convention. Dans ce cas, le certificat doit être présenté `a la section consulaire de la mission qui représente ce pays.**

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

# CERTIFICATE

## No. QS6 086625 0015 Rev. 00

**Certificate Holder:** **Medtronic Inc.**
710 Medtronic Parkway N.E.
Minneapolis MN 55432
USA

**Certification Mark:**

**Scope of Certificate:** **See Page 2 for Overall Scope Statement.**

The Minnesota of State

As a registered Notary Public for the State of Minnesota, I hereby certify that this is a true and accurate copy of the original document. The orginal is filed at Medtronic, Inc.

**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 https://www.tuev-sued.de/product-testing/certificates

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

**DUNS No:** **00-626-1481**

**Effective Date:** **2019-02-22**

**Expiry Date:** **2022-02-21**

CINDI A. BIGELBACH
Notary Public
State of Minnesota
My Commission Expires
January 31, 2022

Cindi A Bigelbach
4/16/19


**Date of Issue:** 2019-03-15

( Arie Henkin )
Manager, Certification Body MHS

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# CERTIFICATE

## No. QS6 086625 0015 Rev. 00

**Regulatory Requirements:** **Audit/Certification Criteria**

**Australia**
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

**Brazil**
- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

**Canada**
- Medical Device Regulations SOR/98-282, Part 1

**United States**
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820
- 21 CFR Part 821

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

**Overall Scope Statement:**

**Design, Development, Manufacturing and Distribution of Implantable Defibrillators, Implantable Pulse Generators, Pacemaker Delivery Systems, Leads for Brady IPGs, Tachy ICDs and Heart Failure Treatment, and Lead Introducers, Guidewires, Stylets, Adapters and Cables for AIMDs, Diagnostic and Ablation Catheters, Ablation Systems, External Pulse Generators, Implantable Monitoring and Recording Systems, Programmers and Application Software (External), Software and Hardware Systems used for Acquisition and Management of ECG and Cardiac Device Data, Fully Absorbable Implantable Antibacterial Envelopes Coated with Ancillary Medicinal Substances**


**Date of Issue:** 2019-03-15

( Arie Henkin )
Manager, Certification Body MHS

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MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

# CERTIFICATE

## No. QS6 086625 0015 Rev. 00

**Facility(ies):**

Medtronic Inc.
710 Medtronic Parkway N.E., Minneapolis MN 55432, USA

Medtronic Inc.
8200 Coral Sea St., Mounds View MN 55112, USA

Medtronic Inc.
7000 Central Avenue N.E., Minneapolis MN 55432, USA

Medtronic Inc.,
800 53rd Avenue NE, Columbia Heights MN 55421, USA

Medtronic Europe Sàrl
Route du Molliau 31, Case Postale, 1131 Tolochenaz,
SWITZERLAND

Medtronic Singapore Operations Pte. Ltd.
49 Changi South Avenue 2, Nasaco Tech Centre, Singapore
486056, SINGAPORE

Medtronic Puerto Rico Operations Co., Villalba
Rd. 149, Km. 56.3, Call Box 6001, Villalba, PR 00766, USA

Medtronic Puerto Rico Operations Co., Juncos
Road 31, Km. 24, Hm 4, Ceiba Norte Industrial Park, Juncos,
PR 00777, USA

**Facility Scopes:**

**Medtronic Inc.**
710 Medtronic Parkway N.E., Minneapolis MN 55432, USA

Legal Entity with Management Oversight Responsibility for All Quality Related Matters
DUNS No: 00-626-1481


**Date of Issue:** 2019-03-15

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Manager, Certification Body MHS

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# CERTIFICATE

## No. QS6 086625 0015 Rev. 00

**Medtronic Inc.**
8200 Coral Sea St., Mounds View MN 55112, USA

Design, Development, Manufacturing and Distribution of Implantable Defibrillators, Implantable Pulse Generators, Pacemaker Delivery Systems, Leads for Brady IPGs, Tachy ICDs and Heart Failure Treatment, and Lead Introducers, Guidewires, Stylets, Adapters and Cables for AIMDs, Diagnostic and Ablation Catheters, Ablation Systems, External Pulse Generators, Implantable Monitoring and Recording Systems, Programmers and Application Software (External), Software and Hardware Systems used for Acquisition and Management of ECG and Cardiac Device Data, Fully Absorbable Implantable Antibacterial Envelopes Coated with Ancillary Medicinal Substances
DUNS No: 13-620-1675

**Medtronic Inc.**
7000 Central Avenue N.E., Minneapolis MN 55432, USA

Manufacturing of Leads for Brady IPGs, Tachy ICDs and Heart Failure Treatment, and Adaptors and Cables for AIMDs, Fully Absorbable Implantable Antibacterial Envelopes Coated with Ancillary Medicinal Substances
DUNS No: 79-698-6144

**Medtronic Inc.**
800 53rd Avenue N.E., Columbia Heights MN 55421, USA

Servicing of Programmers, External Patient Monitors, External Pulse Generators and RF Generators
DUNS No: 96-837-2008


**Date of Issue:** 2019-03-15

( Arie Henkin )
Manager, Certification Body MHS

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# CERTIFICATE

## No. QS6 086625 0015 Rev. 00

**Medtronic Europe Sàrl**
Route du Molliau 31, Case Postale, 1131 Tolochenaz, SWITZERLAND

Manufacturing of Implantable Pulse Generators, Implantable Defibrillators, Implantable Monitoring and Recording Systems
DUNS No: 48-455-9075

**Medtronic Singapore Operations Pte. Ltd.**
49 Changi South Avenue 2, Nasaco Tech Centre, Singapore 486056, SINGAPORE

Manufacturing of Implantable Pulse Generators, Implantable Defibrillators, Implantable Monitoring and Recording Systems, Leads for Brady IPGs, Tachy ICDs and Heart Failure Treatment
DUNS No: 59-520-6000

**Medtronic Puerto Rico Operations Co., Villalba**
Rd. 149, Km. 56.3, Call Box 6001, Villalba, PR 00766, USA

Manufacturing and Distribution of Leads for Brady IPGs, Tachy ICDs and Heart Failure Treatment, Diagnostic and Ablation Catheters, Lead Introducers, Guidewires, Stylets, Adapters and Cables for AIMDs
DUNS No: 09-045-2434

**Medtronic Puerto Rico Operations Co. Juncos**
Road 31, Km. 24, Hm 4, Ceiba Norte Industrial Park, Juncos, PR 00777, USA

Manufacturing and Distribution of Implantable Pulse Generators, Implantable Defibrillators, Implantable Monitoring and Recording Systems
DUNS No: 08-016-4360


**Date of Issue:** 2019-03-15

( Arie Henkin )
Manager, Certification Body MHS

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