

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

№ 42213



1. Country: *United States of America*

This public document

2. has been signed by Carl Fischer

3. acting in the capacity of Director, Office of Compliance

4. bears the seal/stamp of U.S. Department of Health and Human Services

Certified

5. at Washington, D.C.

6. the fourth of February, 2016

7. by *Assistant Authentication Officer, United States Department of State*

8. No. 16017083-1

9. Seal/Stamp:

10. Signature:

Patrick O. Hatchett



DEPARTMENT OF HEALTH & HUMAN SERVICES



Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

42213

Certificate No. 7666-9-2015

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

See Attached List

(Two Pages)

Name of Manufacturer/Distributor, Address

See Attached List

(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Carl Fischer, Ph.D.
Director
Division of International Compliance Operations
Office of Compliance
Center for Devices and Radiological Health

This certificate is valid from October 26, 2015 to **October 25, 2017.**



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Public Health Service

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Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Owner Operator

MEDTRONIC INC.
710 Medtronic Pkwy.
Minneapolis, MN USA 55432

Name of Manufacturer

Specification Developer
MEDTRONIC, INC.
8200 Coral Sea Street NE
Mounds View, MN USA 55112

MEDTRONIC PUERTO RICO OPERATIONS CO., VILLALBA
RD. 149, KM. 56.3
Call Box 6001
Villalba, PR USA 00766

Medtronic Monitoring, Inc.
1410 Energy Park Dr
Saint Paul, MN USA 55108

—END OF MANUFACTURER/DISTRIBUTOR LIST—



Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Certificate No. 7666-9-2015

Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 2

Name of Manufacturer

MEDTRONIC PUERTO RICO OPERATIONS CO., VILLALBA
RD. 149, KM. 56.3
Call Box 6001
Villalba, PR USA 00766

Name of Product(s)

Implantable Leads:

Model 4193 - Attain OTW
Model 4194 - Attain Bipolar OTW
Model 4195 - Attain Starfix
Model 4196 - Attain Ability
Model 4296 - Attain Ability Plus
Model 4396 - Attain Ability Straight
Model 4298 - Attain Performa
Model 4398 - Attain Performa Straight
Model 4598 - Attain Performa S
Models 4073, 4074, 4574 - CapSure Sense
Models 4965, 4968 - CapSure Epi
Models 4076, 5076 CapSure Fix Novus
Model 5076 - CapSure Fix Novus MRI SureScan
Model 5086MRI - CapSure Fix MRI SureScan
Model 5568 - CapSure Fix
Models 4092, 4592, 5092, 5592, 5594 - CapSure SP Novus
Models 5038, 5038S, 5038L - CapSure VDD-2
Models 5054, 5554 - CapSure Z Novus
Model 6996SQ - Subcutaneous
Model 5071 - Screw-in Pacing
Model 3830 - SelectSecure
Model 6935, 6935M - Sprint Quattro Secure S
Model 6944 - Sprint Quattro
Model 6947, 6947M - Sprint Quattro Secure
Model 5072 - SureFix
Model 6937, 6937A Transvene SVC
Model 6935M MRI - Sprint Quattro Secure S MRI SureScan
Model 6947M MRI - Sprint Quattro Secure MRI SureScan

Accessories:

Model 5866-23 - Lead Adaptor Kit
Model 6056 - Pinch-on Tool
Model 6056M - Lead Accessory Kit
Model 6920 - Sizing Sleeve Kit
Model 5867-3M - Lead End Cap Kit
Models 6717, 6719, 6725 - Pin Plug Kit
Model 6701 - Lead End Cap
Model 6925 - Sizing Sleeve Kit
Model 6295 - Left Heart Accessory Kit
Model 6985M - Temporary Lead Extender Kit
Model 5873C - Service Kit
Model 5873W - Wrench Kit
Models 6048, 6052, 6054, 6057, 6082, 6091, 6093, 6094, 6254, 6282, 6293 - Stylets
Model 080118 - Medical Adhesive

Name of ManufacturerSpecification Developer

MEDTRONIC, INC.
8200 Coral Sea Street NE
Mounds View, MN USA 55112





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Certificate to Foreign Government - Name of Product(s) Attachment Page 2 of 2

Name of Product(s)

Model 6721 S/M/L - Epicardial Patch
Models 5318, 5348, 5388 Implantable Pulse Generators and accessories
Models 5866-9M, 5866-24M, 5866-37M, 5866-38M, 5866-40M - Lead Adaptor Kit
Model 6984M Lead Extender Kit
Model 6996T - Tunneling Tool
Model 10626 - Epicardial Lead Implant tool
Model 6726 - DF-1-Y-Adaptor/Extender Kit
Model 6232ADJ - Adjustable Slitter
Model 6230UNI - Universal II Slitter
Model 6248VAL - Adjustable Valve
Model 6215 - Attain Venogram Balloon Catheter
Model 2067 - RF Head Carelink Programmer
Model 2090 and accessories - Carelink Programmer
Model 2290 and accessories - Analyzer
Model 5441 - Disposable Cover
Model 6177 - Sterile Sleeve
Model 5328 - Programmable Stimulator
Model 6191 - Patient Activator
Model 5019 - HV Splitter/adaptor kit
Model LINGTOOL - Reveal LING Insertion Tools
Percutaneous Lead Introducer (PLI)
Models - 6207-S1, 6207-S5, 6207-D1
Models - 6208-S1, 6208-S5, 6208-D1 - PLI
Models - 6209-S1, 6209-S5, 6209-D1 - PLI
Models - 6210-S1, 6210-S5, 6210-D1 - PLI
Models - 6211-S1, 6211-S5, 6211-D1 - PLI
Models - 6212-S1, 6212-S5, 6214-S1, 6214-S5 - PLI
Models - 6207-BTK1, 6207-BTK5, 6207-BTKL1, 6207-BTK-D1 - Solo-Trak-KR PLI
Models - 6208-BTK1, 6208-BTK5, 6208-BTKL1, 6208-BTK-D1 - Solo-Trak-KR PLI
Models - 6209-BTK1, 6209-BTK5, 6209-BTKL1, 6209-BTK-D1 - Solo-Trak-KR PLI
Models - 6210-BTK1, 6210-BTK5, 6210-BTKL1, 6210-BTK-D1 - Solo-Trak-KR PLI
Models - 6211-BTK1, 6211-BTK5, 6211-BTK-D1 - Solo-Trak-KR PLI
Models - 6212-BTK1, 6212-BTK5, 6214-BTK1, 6214-BTK5 - Solo-Trak-KR PLI

Name of Manufacturer

Medtronic Monitoring, Inc.
1410 Energy Park Dr
Saint Paul, MN USA 55108

Name of Product(s)

External Cardiac Monitor:

Model SEEQ11 - SEEQ External Cardiac Monitor (ECM) 1 Week Kit
Model SEEQ12 - SEEQ External Cardiac Monitor (ECM) 2 Week Kit
Model SEEQ13 - SEEQ External Cardiac Monitor (ECM) 3 Week Kit
Model SEEQ14 - SEEQ External Cardiac Monitor (ECM) 4 Week Kit
Model SEEQ1E - SEEQ Single Wearable Sensor Single Wearable Sensor
Model SEEQ1T - SEEQ Single Transmitter Single Transmitter

END OF PRODUCT LIST

