



Certificate No. 1209-2-2016

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

(Six 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 February 09, 2016 to February 08, 2018.





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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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

MEDTRONIC PERFUSION SYSTEMS
7611 Northland Dr
Minneapolis, MN USA 55428

Manufacturing Facility

Medtronic Mexico S. de R.L. de CV
Av. Paseo Cucapah 10510 El Lago
Tijuana, Baja California MEXICO C.P. 22210

Manufacturing Facility

MEDTRONIC PERFUSION SYSTEMS
18501 E Plaza Dr
PARKER, CO USA 80134

-----END OF MANUFACTURER/DISTRIBUTOR LIST-----





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MEDTRONIC INC.

710 Medtronic Pkwy.

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MEDTRONIC PERFUSION SYSTEMS

7611 Northland Dr

Minneapolis, MN USA 55428

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Av. Paseo Cucapah 10510 El Lago

Tijuana, Baja California MEXICO C.P. 22210

Manufacturing Facility

MEDTRONIC PERFUSION SYSTEMS

18501 E Plaza Dr

PARKER, CO USA 80134

Name of Product(s)

COAGULATION INSTRUMENT

303-58 - ACT Cleaning Kit

313-11 - Temperature Verification Cartridge

31363 - ACTtrac®

ACT100 - ACT Plus®, 100-120V

ACT200 - ACT Plus®, 200-240V

ACT20001 - ACT Plus®, 200-240V

ACT20002 - ACT Plus®, 200-240V

ACT20003 - ACT Plus®, 200-240V

ACT20004 - ACT Plus®, 200-240V

ACT20005 - ACT Plus®, 200-240V

ACT20006 - ACT Plus®, 200-240V

ACT20008 - ACT Plus®, 200-240V

ACT2000BV - ACT Plus®, 200-240V

ACT20024 - ACT Plus®, 200-240V

ACT20041 - ACT Plus®, 200-240V

ACT20046 - ACT Plus®, 200-240V

ACTEDM - ACT Plus® External Data Manager Software

ACTSC - ACT Bar Code Scanner

ACTSC66 - ACT Bar Code Scanner

ACTSCC4 - ACT Bar Code Scanner

THERMAL REGULATING SYSTEM

370 - Bio-Cal® 370

370I - Bio-Cal® 370

CARDIOPULMONARY BYPASS PUMP CONTROL

100 - Emergency Hand Crank

150 - Emergency Hand Crank

550 - Bio-Console®

560 - Bio-Console®

560A - External Drive Motor

540T - External Drive Motor

550I - Bio-Console®

550M - Bio-Console®, Modular

560BC - 560 Pump Speed Controllers

560BC1 - Bio-Console 560BC1 Speed Controller

560BCS - 560 v1.5 Pump Speed Controller

560BCS1 - Bio-Console 560BCS1 Speed Controller





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560MP1510 - System 560MP15 Manual Power Cord M928131A002
560MP1520 - System 560MP15 Manual Power Cord M928131A004
560SMU - System, 560 Safety Module
A09075001 - 560 User Interface
A09075002 - 560 v1.5 User Interface
A09075003 - User Interface Assy. 560 v1.6
ACM100 - AutoClamp Interface Module
ACM200 - AutoClamp Interface Cable
ACM300 - Air Supply Line
ACMPM - AutoClamp Module Pole Mount
ACS500 - AutoClamp System Kit
BD14 - Pediatric Bubble Detector Cable
BD38 - Adult Bubble Detector Cable
E560BCS - Console E560BCS Eval Controller
E560BCS1 - Console E560BCS Eval Controller
HCS150 - Handcrank Stand
HC150A - Handcrank
LS100 - Level Sensor
LST - Level Sensor Tape
RTC100 - Remote Tube Clamp
RTC200 - TX50 Remote Tube Clamp Holder
RTCMA - Remote Tube Clamp Mount Adapter
CARDIOPULMONARY BYPASS PUMP CONTROL (Refurbished)
R560BCS - Console R560BCS Refurb Controller (Refurbished)
R560BCS1 - Console R560BCS Refurb Controller (Refurbished)
TEMPERATURE PROBE
61399400072 - Temperature Probe
BLOOD FLOW PROBE
DP38 - Bio-Probe® Disposable Insert
DP38P - Bio-Probe® Disposable Insert
DP38T - Bio-Probe® Trillium™ Adult Flow Probe 3/8
DP38PT - Bio-Probe® Trillium™ Pediatric Flow Probe 1/4
TX50 - Bio-Probe® Flow Transducer - Adult
TX50P - Bio-Probe® Flow Transducer - Pediatric
CB2980 - Bio-Probe® Adult Flow Probe 3/8
CB2980POLY - Bio-Probe® Adult Flow Probe 3/8
CARDIOPULMONARY BYPASS IN-LINE BLOOD GAS SENSOR
90483 - Optical Cable Assembly
95198-003 - Bio-Trend® Oxygen Saturation & Hematocrit System 110V
95198-004 - Bio-Trend® Oxygen Saturation & Hematocrit System 220V
1145267-1 - Bulk Non-Sterile Assembly, TMC50
1145267-501 - Bulk Non-Sterile Assembly, TMC38
1145267-502 - Bulk Non-Sterile Assembly, TMC25
1473R1 - TMC25 Tri-Optic Measurement Cell, 1/4" x 1/4" with 6" Extension
1474R1 - TMC38 Tri-Optic Measurement Cell, 3/8" x 3/8" with 6" Extension
1475R1 - TMC50 Tri-Optic Measurement Cell, 1/2" x 1/2" with 6" Extension
CB4714R1 - TMC25 Tri-Optic Measurement Cell, 1/4" x 1/4" with 6" Extension with Carmeda® BioActive Surface
CB4715R1 - TMC38 Tri-Optic Measurement Cell, 3/8" x 3/8" with 6" Extension with Carmeda® BioActive Surface
CB4716R1 - TMC50 Tri-Optic Measurement Cell, 1/2" x 1/2" with 6" Extension with Carmeda® BioActive Surface
TMC25 - Tri-Optic Measurement Cell, 1/4"
TMC25T - Tri-Optic Measurement Cell, 1/4" x 1/4" with Trillium® BioSurface
TMC38 - Tri-Optic Measurement Cell, 3/8"
TMC38T - TMC Tri-Optic Measurement Cell, 3/8" x 3/8" with Trillium® BioSurface
TMC50 - Tri-Optic Measurement Cell, 1/2"
TMC50T - TMC Tri-Optic Measurement Cell, 1/2" x 1/2" with Trillium® BioSurface





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CARDIOPULMONARY BLOOD PUMP

BP-50 - Bio-Pump® Centrifugal Pump, Pediatric
BPX-80 - Bio-Pump® Plus Centrifugal Blood Pump
CBBPX-80 - Bio-Pump® Plus Centrifugal Blood Pump with Carmeda® BioActive Surface
AP40 - Affinity® CP Centrifugal Blood Pump
BBAP40 - Affinity™ CP Centrifugal Blood Pump with Balance™ Biosurface
CBAP40 - Affinity™ CP Centrifugal Blood Pump with Carmeda® BioActive Surface
AP40AST - Affinity™ CP Adapter
BPX-80T - Bio-Pump® Plus Centrifugal Blood Pump with Trillium®

ARTERIAL FILTER

351 - AFFINITY® 38µ Arterial Blood Filter with Bypass Loop
352 - AFFINITY® 38µ Arterial Blood Filter without Bypass Loop
353 - AFFINITY® 20µ Arterial Blood Filter with Bypass Loop
354 - AFFINITY® 20µ Arterial Blood Filter without Bypass Loop
1338 - Arterial Blood Filter, 20 Micron Pediatric
61399401153 - Arterial Filter w/Bypass Loop, 352
61399409503 - Arterial Filter, 354
351T - AFFINITY® 38µ Arterial Blood Filter with Bypass Loop with Trillium®
353T - AFFINITY® 20µ Arterial Blood Filter with Bypass Loop with Trillium®
CB1338 - Pediatric Arterial Blood Filter with Carmeda® BioActive Surface, 20 Micron
CB351 - AFFINITY® 38µ Arterial Blood Filter with Carmeda® BioActive Surface
CB353 - AFFINITY® 20µ Arterial-Filter Loop Carmeda® BioActive Surface
S4014 - Affinity® Pediatric Arterial Filter
BB4014 - Affinity Pixie™ Arterial Filter with Balance™ Biosurface
CB4014 - Affinity® Pediatric Arterial Filter with Carmeda® BioActive Surface
BB851 - Affinity® AF100 Arterial Filter with Balance® Biosurface
CB851 - Affinity® AF100 Arterial Filter with Carmeda® BioActive Surface

CARDIOPULMONARY BYPASS HEAT EXCHANGER

BIOtherm - Heat Exchanger
ECMOtherm II - Heat Exchanger
CBXP41 - MYOtherm XP® Cardioplegia Delivery System with Carmeda® BioActive Surface
CBXP41B - MYOtherm XP® Cardioplegia Delivery Systems with Carmeda® BioActive Surface
D1080A - Cardioplegia Delivery Set, 2:1
D1081A - Cardioplegia Delivery Set, 4:1
P9545 - Cardioplegia Extension Line
XP41 - MYOtherm XP® Cardioplegia Delivery System
XP41-B - MYOtherm XP® Cardioplegia Delivery System

HOLDERS

1072 - Holder for AFFINITY® Oxygenator (Stand Alone)
1093 - Holder for AFFINITY® Oxygenator with Integrated CVR
1095 - Short Arm Mast Accessory for use with AFFINITY® Oxygenator Holders
1302 - Minimax® Plus Hollow Fiber Oxygenator Holder
1303 - Minimax® Venous Reservoir Bag Holder
1304 - Minimax® Hardshell Venous Reservoir Holder
95229 - Holder for AFFINITY® Integrated CVR with Extended Mast for 540T
95230 - Holder for AFFINITY® Oxygenator (Stand Alone) with Extended Mast for 540T
95231 - Extended Mast Only, for AFFINITY® Holders and 540T
95232 - AFFINITY® Stand Alone Oxygenator Top Clamp with Carmeda® BioActive Surface
95288 - Resting Heart® System Holder
61399401093 - Holder for AFFINITY® Oxygenator, 341
61399401119 - AFFINITY® Filter Holder
61399408182 - MyOtherm XP® Holder
AUH2093 - Affinity Orbit Holder
AMH2014 - Affinity Manifold Holder
HR4014 - Holder for Affinity Pixie™ Pediatric Arterial Filter
MVR-SH - MVR Holder for Venous Reservoir Bag
AUTOTRANSFUSION APPARATUS
E302 - Reservoir Holder, EL Series Hardshell





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AUTOMATED HEPARIN ANALYZER

30514 - HMS Plus Instrument, 100-120V

30515 - HMS Plus, 200-240V

30517 - HMS Plus, 200-240V

30518 - HMS Plus, 200-240V

30522 - HMS Plus, 200-240V

30524 - HMS Plus, 200-240V

30526 - HMS Plus, 200-240V

30527 - HMS Plus, 200-240V

30528 - HMS Plus, 200-240V

300-10 - Temperature Verification Cartridge, HMS Plus

304-01POR - Heparin Assay, 4 CH, Red

304-02POR - Heparin Assay, 4 CH, Yellow

304-03POR - Heparin Assay, 4 CH, Tan

304-04POR - Heparin Assay, 4 CH, Silver

304-05POR - Heparin Assay, 4 CH, Blue

304-06POR - Heparin Assay, 4 CH, Green

304-07POR - Heparin Assay, 6 CH, Orange

304-08POR - Heparin Assay, 6 CH, Gold

304-09POR - Heparin Assay, 6 CH, White

304-10POR - Heparin Assay, 6 CH, Purple

304-11POR - Heparin Assay, 6 CH, Black

304-20POR - HDR Cartridge, 6 Channel

304-30 - HR-ACT Cartridge, 2 Channel

306-01POR - HMS Control, Red/Yellow

306-02POR - HMS Control, Tan/Silver

306-03POR - HMS Control, Blue/Gold

306-04POR - HMS Control, Green/White

306-05POR - HMS Control, Orange

306-09POR - HMS Control, Purple/Black

313-50 - HEPline Kit

HMSPLUSEDM - HMS Plus External Data Manager

HMSPLUSSC - HMS Bar Code Scanner, Domestic

HMSPLUSSCRS - HMS Bar Code Scanner

HMSPLUSSCYY - HMS Bar Code Scanner

MULTIPURPOSE SYSTEM FOR IN-VITRO COAGULATION STUDIES

313-51 - HEPtrac

550-01 - CLOTtrac CWB Control

550-07 - CLOTtrac HR Control

550-11 - CLOTtrac Calcium Chloride, 5 ML

550-12 - CLOTtrac HTC Control

550-13 - CLOTtrac Pack (HR and HR AB)

CLINICAL ELECTRONIC THERMOMETER

9012-147T - Cable adapter for TM-147T

CARDIOPULMONARY BYPASS OXYGENATOR

2503 - Closed Chest Support

2504 - Closed Chest Support

2505 - Closed Chest Support

2506 - Closed Chest Support

2507 - Closed Chest Support

CB2503 - Closed Chest Support with Carmeda® BioActive Surface

CB2505 - Closed Chest Support with Carmeda® BioActive Surface

CB2506 - Closed Chest Support with Carmeda® BioActive Surface

CB2507 - Closed Chest Support with Carmeda® BioActive Surface

3301 - Minimax Plus® Hollow Fiber Oxygenator with Separate Filtered Hardshell Reservoir

3381 - Minimax Plus® Hollow Fiber Oxygenator with Improved Plasma Resistant Fiber (PRF)

CB1374 - Minimax® Venous Reservoir Bag with Carmeda® BioActive

Surface, 1/4" Outlet 110-230 ml Volume, 105 Micron Screen





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CB3381 - Minimax Plus® Hollow Fiber Oxygenator with Carmeda® BioActive Surface
511 - AFFINITY® NT Oxygenator with Plasma Resistant Fiber (PRF)
511T - AFFINITY® NT Oxygenator with Trillium® BioPassive Surface
541 - AFFINITY® NT Integrated CVR/Membrane Oxygenator with Plasma Resistant Fiber (PRF)
541-R - AFFINITY® NT Integrated CVR/Membrane Oxygenator with Plasma Resistant Fiber (PRF)
541T - AFFINITY® NT Integrated CVR Oxygenator with Trillium® Biosurface
541T-R - AFFINITY® NT Integrated Oxygenator with (PRF) with Trillium® Biosurface and Integrated AFFINITY® NT Trillium® CVR
541TT - AFFINITY® NT Integrated Oxygenator with Cardiotomy Venous Reservoir with Trillium®
541TT-R - AFFINITY® NT Integrated Oxygenator with PRF Fiber with Trillium® Biosurface and Integrated AFFINITY® NT Trillium® CVR
CBP211 - Affinity Pixie™ Hollow Fiber Oxygenator with Carmeda® BioActive Surface
BBP211 - Affinity Pixie™ Hollow Fiber Oxygenator with Balance™ Biosurface
BBP241 - Affinity Pixie™ Hollow Fiber Oxygenator and Cardiotomy/Venous Reservoir with Balance™ Biosurface
CBP241 - Affinity Pixie™ Hollow Fiber Oxygenator and Cardiotomy/Venous Reservoir with Carmeda® BioActive Surface
CB511 - AFFINITY® NT Oxygenator with PRF with Carmeda® BioActive Surface
CB541 - AFFINITY® NT Integrated CVR/Membrane Oxygenator (PRF) Oxygenator with Carmeda® BioActive Surface
BB811 - Affinity Fusion® Oxy w/ Integrated Arterial Filter and Balance® Biosurface
CB811 - Affinity Fusion® Oxy w/ Integrated Arterial Filter and Carmeda® BioActive Surface
ATP210 - Affinity Temperature Probe
CB1386 - MVR Venous Reservoir Bag with Carmeda® BioActive Surface
CBMVR800 - MVR Venous Reservoir Bag 800ml with Carmeda® BioActive Surface
CBMVR1600 - MVR Venous Reservoir Bag 1,600 ml with Carmeda® BioActive Surface
CB4627 - Bio-Probe® Pediatric Flow Probe 1/4
CBBP-50 - Bio-Pump® Centrifugal Pump with Carmeda® BioActive Surface, Pediatric RESERVOIR
321 - AFFINITY® Venous Reservoir Bag with Recirculation Line
540 - AFFINITY® NT CVR
540T - AFFINITY® Cardiotomy/Venous Reservoir with Filter (CVR) with Trillium® Biosurface
CB841 - Affinity Fusion® Oxygenator with Integrated Arterial Filter and Carmeda® BioActive Surface and Cardiotomy/Venous Reservoir with Balance® Biosurface
BB841 - Affinity Fusion® Oxygenator with Integrated Arterial Filter and Cardiotomy/Venous Reservoir with Balance® Biosurface
EL2120 - Reservoir, Blood Collection, Hardshell, 4 Liter, 120 Micron
EL240 - Reservoir, Blood Collection, Hardshell, 4 Liter, 40 Micron
EL400 - Reservoir, Cardiotomy, Hardshell, 4 Liter, 120 Micron
EL402 - Reservoir, Cardiotomy, Hardshell, 4 Liter, 20 Micron
EL404 - Reservoir, Cardiotomy, Hardshell, 4 Liter, 40 Micron
MVR1600 - MVR Venous Reservoir Bag, Collapsible, 1,600 ml
MVR800 - MVR Venous Reservoir Bag, Collapsible, 800 ml
711 - Resting Heart® System Module
AAR1000 - Resting Heart® System Automatic Air Removal Controller
1350 - INTERSEPT® Cardiotomy Reservoir - 2,600 ml
1351 - INTERSEPT® Cardiotomy Reservoir with Filter - 2,600 ml
CB1351 - INTERSEPT® Filtered Cardiotomy Reservoir - 2,600 ml
1374 - Minimax® Venous Reservoir Bag with 1/4" Outlet
1375 - INTERSEPT® Venous Reservoir Bag, 1,000 ml
1386 - MAXIMA® Venous Reservoir Bag
1143009-1 - Non-Sterile 1386
1143010-501 - Non-Sterile 1375
1143010-503 - Non-Sterile 1374, Bulk
1143010-504 - Non-Sterile 1385
1143016-1 - MVR800 Bulk Nonsterile
1143016-501 - MVR1600 Bulk Nonsterile





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1143016-502 - MVR800 N/S W/O Temperature Probe
1143016-503 - MVR1600 N/S W/O Temperature Probe
RV-1500-1 - Venous Reservoir Bag, 1,500 ml
RV-500-1 - Venous Reservoir Bag, 500 ml
RV-500-3 - Venous Reservoir Bag, 500 ml
61399401032 - MYOthem XP® Delivery Line
61399404996 - MyOthem XP® 4:1
61399405331 - MyOthem XP® 4:1B
XP41BT - MYOthem XP® 4:1BT Cardioplegia Delivery System with Trillium® Biopassive
Surface with Bypass Loop
XP41T - MYOthem XP® 4:1T Cardioplegia Delivery System with Trillium® Biopassive Surface
CPB CATHETER, CANNULA, OR TUBING
RCL841 - Affinity Fusion™ Recirculation Line
R-14 - Silicone Assist Reservoir (Bladder Bag)
R-38 - Silicone Assist Reservoir
CARDIOPULMONARY BYPASS DEFOAMER
113305604 - AFFINITY® VARD with Carmeda Bioactive Surface
M941143A001 - Purgeline Uncoated
M941142A001 - Holding Bag with Carmeda Bioactive Surface
M941141A001 - Holding Bag Uncoated
M940880A001 - Utility Connector with Carmeda Bioactive Surface
M942593A001 - Utility Connector Uncoated
1316 - Minimax® Filtered Hardshell Venous Reservoir with Integral Cardiomy Filter
ACTIVATED BLOOD CLOTTING TIME
402-01 - Cartridge, LR-ACT
402-02 - Cartridge, RACT
402-03 - Cartridge, HR-ACT
402-07 - Cartridge, HR HTC, Boxed
550-08 - CLOTtrac HR Abnormal Control
550-09 - CLOTtrac LR Abnormal Control
550-10 - CLOTtrac RACT Abnormal Control
ACTFILHR - HR ACT Easy Fill Device
ACTFILLR - LR ACT Easy Fill Device

-----END OF PRODUCT LIST-----

