



23 April 2015

## CERTIFICATE OF FREE SALE

### To Whom It May Concern

The Health Products Regulatory Authority hereby certifies that:

- 1) The active implantable medical devices specified in the attached schedule are manufactured in Ireland by Medtronic Ireland, Parkmore Business Park West, Galway, Ireland. Manufacturer (as defined in the Medical Devices Directive 93/42/EEC) is Medtronic, Inc., 710 Medtronic Parkway, Minneapolis, MN 55432, U.S.A.
- 2) The active implantable medical devices specified in the attached schedule are CE marked in accordance with the European Communities (Active Implantable Medical Devices) Regulations, 1990 (which transposed the Active Implantable Medical Devices Directive 90/385/EEC into Irish Law) and may be marketed and
- 3) Exportation of the active implantable medical devices listed in the attached schedule is not prohibited.
- 4) The granting of this certificate is based on the information available to the Health Products Regulatory Authority on the date of issue of the certificate.

**Issued To:** Medtronic Ireland  
Parkmore Business Park West  
Galway  
Ireland

**Expiry Date:** 23 April 2020



**Patrick Keating**  
Compliance Department  
Health Products Regulatory Authority  
CFS007067

Page 1 of 5

## MEDICAL DEVICE SCHEDULE

Item Number/Product	Description of Device
6216A	Attain LDS 6216A Left Heart Delivery System
6218A	Attain ACCESS 6218A Left Heart Delivery System
6218A-45S	Attain 6218A-45S Guide Catheter for Left Heart Delivery
6218A-50S	Attain 6218A-50S Guide Catheter for Left Heart Delivery
6216A-MB2	Attain 6216A-MB2 Guide Catheter for Left Heart Delivery
6218A-AM	Attain 6218A-AM Guide Catheter for Left Heart Delivery
6216A-MP	Attain 6216A-MP Guide Catheter for Left Heart Delivery
6218A-57S	Attain 6218A-57S Guide Catheter for Left Heart Delivery
6218A-EH	Attain 6218A-EH Guide Catheter for Left Heart Delivery
C304-S59	SelectSite C304-S59 Deflectable Catheter System
C304-L69	SelectSite C304-L69 Deflectable Catheter System
C304-XL74	SelectSite C304-XL74 Deflectable Catheter System
6248DEL90D	Attain Select II 6248DEL90D Delivery Catheter System
6248DEL130D	Attain Select II 6248DEL130D Delivery Catheter System
6248DEL90DS	Attain Select II 6248DEL90DS Delivery Catheter System
6248DEL90DL	Attain Select II 6248DEL90DL Delivery Catheter System
6248DEL130DL	Attain Select II 6248DEL130DL Delivery Catheter System
6227DEF	Attain 6227DEF Deflectable Catheter Delivery System
6250C	Attain Command 6250C Left-Heart Delivery System

## MEDICAL DEVICE SCHEDULE

Item Number/Product	Description of Device
6250S	Attain Command 6250S Left-Heart Delivery System
6250-45S	Attain Command 6250-45S Guide Catheter for Left-Heart Delivery
6250-50S	Attain Command 6250-50S Guide Catheter for Left-Heart Delivery
6250-57S	Attain Command 6250-57S Guide Catheter for Left-Heart Delivery
6250-AM	Attain Command 6250-AM Guide Catheter for Left-Heart Delivery
6250-EH	Attain Command 6250-EH Guide Catheter for Left-Heart Delivery
6250-EHXL	Attain Command 6250-EHXL Guide Catheter for Left-Heart Delivery
6250-MB2	Attain Command 6250-MB2 Guide Catheter for Left-Heart Delivery
6250-MB2X	Attain Command 6250-MB2X Guide Catheter for Left-Heart Delivery
6250-MP	Attain Command 6250-MP Guide Catheter for Left-Heart Delivery
6250-MPR	Attain Command 6250-MPR Guide Catheter for Left-Heart Delivery
6250-MPX	Attain Command 6250-MPX Guide Catheter for Left-Heart Delivery
C315S4	C315S4 Delivery Catheter
C315S5	C315S5 Delivery Catheter
C315S10	C315S10 Delivery Catheter
C315J	C315J Delivery Catheter

## MEDICAL DEVICE SCHEDULE

Item Number/Product	Description of Device
C315HIS	C315HIS Delivery Catheter
C315H20	C315H20 Delivery Catheter
C315H40	C315H40 Delivery Catheter
6250VIS	Attain Command + SureValve 6250VIS Left-Heart Delivery System
6250VIC	Attain Command + SureValve 6250VIC Left-Heart Delivery System
6250VI-MB2	Attain Command + SureValve 6250VI-MB2 Guide Catheter for Left Heart Delivery
6250VI-EH	Attain Command + SureValve 6250VI-EH Guide Catheter for Left Heart Delivery
6250VI-EHXL	Attain Command + SureValve 6250VI-EHXL Guide Catheter for Left Heart Delivery
6250VI-MPR	Attain Command + SureValve 6250VI-MPR Guide Catheter for Left Heart Delivery
6250VI-MP	Attain Command + SureValve 6250VI-MP Guide Catheter for Left Heart Delivery
6250VI-AM	Attain Command + SureValve 6250VI-AM Guide Catheter for Left Heart Delivery
6250VI-MB2X	Attain Command + SureValve 6250VI-MB2X Guide Catheter for Left Heart Delivery
6250VI-45S	Attain Command + SureValve 6250VI-45S Guide Catheter for Left Heart Delivery
6250VI-50S	Attain Command + SureValve 6250VI-50S Guide Catheter for Left Heart Delivery
6250VI-57S	Attain Command + SureValve 6250VI-57S Guide Catheter for Left Heart Delivery

## MEDICAL DEVICE SCHEDULE

Item Number/Product	Description of Device
6250VI-MPX	Attain Command + SureValve 6250VI-MPX Guide Catheter for Left Heart Delivery
6250VI-3D	Attain Command + SureValve 6250VI-3D Guide Catheter for Left Heart Delivery
6248VI-90	Attain Select II + SureValve 6248VI-90 Guide Catheter for Left Heart Delivery
6248VI-90S	Attain Select II + SureValve 6248VI-90S Guide Catheter for Left Heart Delivery
6248VI-90L	Attain Select II + SureValve 6248VI-90L Guide Catheter for Left Heart Delivery
6248VI-130	Attain Select II + SureValve 6248VI-130 Guide Catheter for Left Heart Delivery
6248VI-130L	Attain Select II + SureValve 6248VI-130L Guide Catheter for Left Heart Delivery
6248VI-90P	Attain Select II + SureValve 6248VI-90P Guide Catheter for Left Heart Delivery
6248VI-90SP	Attain Select II + SureValve 6248VI-90SP Guide Catheter for Left Heart Delivery
6248VI-130P	Attain Select II + SureValve 6248VI-130P Guide Catheter for Left Heart Delivery