

Declaration of Conformity

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Declaration of Conformity

Legal Manufacturer:	Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN 55432 USA
EC Authorized Representative	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Design Facility:	Medtronic Inc. 8200 Coral Sea Street Mounds View, MN 55112 USA
Manufacturing Facility:	Medtronic Ireland Parkmore Business Park West Galway Ireland
Product Family/ies:	Heart Therapy Delivery Systems
Products:	See Attachment
Classification:	Directive 90/385/EEC (AIMD)
Notified Body	NSAI (0050)
EC Quality Certificate	253.100 issued on 12 June 2002
EC Design Certificate	253.100



I, the undersigned, hereby declare that the Medical Device(s) specified above meet the provisions of Directive 90/385/EEC (AIMD), including amendments issued, which apply to them, as transposed into

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the national laws of the EU member states, as well as the following applicable standards and guidance documents:

- Reference standards listed on the appropriate ER Checklist for each product family.

This declaration is supported by the AIMD, Annex II.3 Approval as well as the EC Design Examination Certificate listed above.

Signed on behalf of the manufacturer exclusively responsible for the Declaration of Conformity:

Place: Medtronic Inc.

Date:

03-MAR-2021

Name: Ryan Calabrese

Title Sr. Regulatory Affairs Director

Signature

Ryan Calabrese



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Products: Heart Therapy Delivery Systems

Model Name	Model No.	Approval Date	Approval Number
SelectSite™ C304-S59 Deflectable catheter system	C304-S59	Mar. 24, 2004 October 11, 2006 October 3, 2008 April 13, 2010 March 3, 2021	253.100/03 253.100/13 253.100/19 253.100/21 253.100/35
SelectSite™ C304-L69 Deflectable catheter system	C304-L69		
SelectSite™ C304-XL74 Deflectable catheter system	C304-XL74	October 11, 2006 October 3, 2008 April 13, 2010 March 3, 2021	253.100/13 253.100/19 253.100/21 253.100/35
SelectSite™ C304-HIS Deflectable catheter system	C304-HIS	July 29, 2020 March 3, 2021	253.100/34 253.100/35
Attain® 6227DEF Deflectable Catheter Delivery System	6227DEF	October 11, 2006 October 3, 2008 March 3, 2021	253.100/13 253.100/19 253.100/35

Model Name	Model No.	Approval Date	Approval Number
C315S4 Delivery Catheter	C315S4	October 28, 2010	253.100/23
C315S5 Delivery Catheter	C315S5	June 28, 2012	253.100/26
C315S10 Delivery Catheter	C315S10	January 21, 2020	253.100/33
C315J Delivery Catheter	C315J	March 3, 2021	253.100/35
C315HIS Delivery Catheter	C315HIS		
C315H20 Delivery Catheter	C315H20		
C315H40 Delivery Catheter	C315H40		



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Model Name	Model No.	Approval Date	Approval Number
Attain Command™ + SureValve™ 6250VIC Left-Heart Delivery System	6250VIC	March 06, 2013 January 21, 2020 March 3, 2021	253.100/27 253.100/33 253.100/35
Attain Command™ + SureValve™ 6250VIS Left-Heart Delivery System	6250VIS		
Attain Command™ + SureValve™ 6250VI-45S Guide Catheter for Left-Heart Delivery	6250VI-45S		
Attain Command™ + SureValve™ 6250VI-50S Guide Catheter for Left-Heart Delivery	6250VI-50S		
Attain Command™ + SureValve™ 6250VI-57S Guide Catheter for Left-Heart Delivery	6250VI-57S		
Attain Command™ + SureValve™ 6250VI-AM Guide Catheter for Left-Heart Delivery	6250VI-AM		
Attain Command™ + SureValve™ 6250VI-EH Guide Catheter for Left- Heart Delivery	6250VI-EH		
Attain Command™ + SureValve™ 6250VI-EHXL Guide Catheter for Left-Heart Delivery	6250VI-EHXL		
Attain Command™ + SureValve™ 6250VI-MB2 Guide Catheter for Left-Heart Delivery	6250VI-MB2		
Attain Command™ + SureValve™ 6250VI-MB2X Guide Catheter for Left-Heart Delivery	6250VI-MB2X		
Attain Command™ + SureValve™ 6250VI-MP Guide Catheter for Left- Heart Delivery	6250VI-MP		
Attain Command™ + SureValve™ 6250VI-MPR Guide Catheter for Left-Heart Delivery	6250VI-MPR		
Attain Command™ + SureValve™ 6250VI-MPX Guide Catheter for Left-Heart Delivery	6250VI-MPX		
Attain Command™ + SureValve™ 6250VI-3D Guide Catheter for Left- Heart Delivery	6250VI-3D		



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Model Name	Model No.	Approval Date	Approval Number
Attain Select™ II + SureValve™ 6248VI-90 Delivery Catheter System	6248VI-90	March 06, 2013 May 27, 2020 March 3, 2021	253.100/27 253.100/36 253.100/35
Attain Select™ II + SureValve™ 6248VI-90S Delivery Catheter System	6248VI-90S		
Attain Select™ II + SureValve™ 6248VI-90L Delivery Catheter System	6248VI-90L		
Attain Select™ II + SureValve™ 6248VI-130 Delivery Catheter System	6248VI-130		
Attain Select™ II + SureValve™ 6248VI-130L Delivery Catheter System	6248VI-130L		
Attain Select™ II + SureValve™ 6248VI-90P Delivery Catheter System	6248VI-90P		
Attain Select™ II + SureValve™ 6248VI-90SP Delivery Catheter System	6248VI-90SP		
Attain Select™ II + SureValve™ 6248VI-130P Delivery Catheter System	6248VI-130P		



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Revision History

Revision	Date	Description of Change
1A	September 2010	Updated to include amendment number for the modified Attain Select II 6248DEL (Amendment # 253.100/22)
1B	November 2010	Updated to include the amendment number for the modified SelectSite™ C304 Deflectable Catheter System (Amendment # 253.100/21) and to add reference to the C315 Delivery Catheter product family (Amendment # 253.100/23)
1C	June 2011	Transpose into new template FTDOP116978-13 rev 1B. Update issue date of the EC Certificates. Remove Attain 6226DEF which is no longer manufactured. Other minor typographical updates.
1D	June 2011	Correct page numbering in the footer. Correction to a Typographical error only. No impact on the DoC content.
1E	November 2011	Updated to include amendment number for the modified Attain 6216A/6218A product family. Minor documentation updates also completed to align model names and formatting with the Design Examination Cert.
1F	July 2012	Updated to include amendment number for implementation of additional sterilisation site (Sterigenics) for the C315 Delivery Catheters and to update title of signatory
1G	March 2013	Updated to add the Attain Command + SureValve and Attain Select II + SureValve product family model names and numbers and their approval details (approval date/approval number).
1H	June 2014	Updated to remove Attain Prevail as product is no longer manufactured or in distribution. Updated also to list the specific model numbers for the Attain Select™ II delivery catheter systems and to reflect re-certification approval by NSAI
1J	November 2015	Updated to include amendment number for implementation of sterilisation cycle 7 for Attain Select™ II delivery catheter systems
1K	May 2017	Updated to reflect extension to current Design Examination certificate & Full Quality Assurance certificate
1L	July 2017	Updated to reflect re-certification approval by NSAI. Revision number corrected in footer.
AA	May 2020	Updated to reflect extension to current Design Examination certificate & Full Quality Assurance certificate for file 253.100.35 under review with NSAI. Update to current template revision FTDOP116978-13 Rev. AB.
AB	August 2020	Update to include amendment number for tip material change for C315 Delivery Catheter, Attain Command + SureValve and Attain Select II + SureValve product families (file 253.100.33, 253.100.36). Add C304-HIS product family model name, number and approval dates as per file 253.100.34.
AC	August 2020	Updated to reflect extension to current Design Examination certificate & Full Quality Assurance certificate for file 253.100.35 under review with NSAI.
AD	November 2020	Update to reflect extension to current Design Examination certificate & Full Quality Assurance certificate for file 253.100.35

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		under review with NSAI.
AE	March 2021	Updated to reflect re-certification approval by NSAI (File 253.100.35). Removed Attain Command, Attain Select II, Attain 6216A/6218A models as product is no longer manufactured or in distribution, and has been removed from the EC Design Examination Certificate as per file 253.100.35. Updated to current template.

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