

From: s22
To: [Devices Clinical](#)
Cc: s22
Subject: FW: Clinical Round 1 - DA-2017-01355-1, DA-2017-01356-1, DA-2017-01357-1, DA-2017-01358-1 [DLM=For-Official-Use-Only]
Date: Monday, 15 May 2017 11:08:26 AM
Attachments: [oledata.mso](#)

Hello s22

Please consider assigning the below request to s22.

Kind Regards

s22

Assistant Director | Devices Applications and Verification Section
 Medical Devices Branch | Medical Devices and Product Quality Division

s22 @health.gov.au | Ph: s22

Therapeutic Goods Administration P.O Box 100, Woden ACT 2606, Australia www.tga.gov.au

From: s22
Sent: Monday, 15 May 2017 10:59 AM
To: Devices Clinical
Cc: s22
Subject: Clinical Round 1 - DA-2017-01355-1, DA-2017-01356-1, DA-2017-01357-1, DA-2017-01358-1 [DLM=For-Official-Use-Only]

Hello s22

The application below has not passed the clinical audit process [D17-344962](#)

Work Management has been updated

Please let me know if you require further information/clarification.

Trim Reference - [D17-326283](#)

Device UPI:	s22 MOMENTUM CRT-D - G125, s22 s22
Sponsor:	Boston Scientific Pty Ltd
Manufacturer:	Cardiac Pacemakers Inc (United States Of America)[9897]
Application ID:	DV-2017-DA-02339-1, DV-2017-DA-02402-1, DV-2017-DA-02403-1 DV-2017-DA-02404-1, DV-2017-DA-02405-1, DV-2017-DA-02406-1 DV-2017-DA-02407-1, DV-2017-DA-02408-1, DV-2017-DA-02411-1
Submission ID:	DA-2017-01355-1, DA-2017-01356-1, DA-2017-01357-1, DA-2017-01358-1 DA-2017-01359-1, DA-2017-01360-1
DAVS Assessor:	s22

Application TRIM	E17-5437, E17-5438, E17-5442, E17-5445, E17-5443, E17-5446 E17-5451, E17-5448, E17-5450
Sponsor's submission TRIM Ref.:	<p>TRIM: D17-324877</p>  <p>CER and CV – saved in Appendix E – Clinical Experience Summary Risk Analysis – saved on Appendix F – Risk Analysis Labels and IFU and Predicate – saved in Appendix C, B and A. (IFU and Labels are identified via the model numbers) Cover letter</p>
Date submitted to TGA:	28/02/2017
Date Referred to Clinical Section:	15/05/2017

Kind Regards

s22

Assistant Director | Devices Applications and Verification Section
Medical Devices Branch | Medical Devices and Product Quality Division

s22 @health.gov.au | Ph: s22

Therapeutic Goods Administration P.O Box 100, Woden ACT 2606, Australia www.tga.gov.au

From: s22
To: s22
Cc: s22 [Devices Clinical](#)
Subject: Clinical Round 3 - DA-2017-01355-1, DA-2017-01356-1, DA-2017-01357-1, DA-2017-01358-1 [DLM=For-Official-Use-Only]
Date: Wednesday, 15 November 2017 10:43:17 AM
Attachments: [\[D17-944425\] DA-2017-01357-1,01358-1,01359-1,01360-1,01356-1,01355-1 - Rd 3 Clinical Assessment - NG4 - Boston Scientific Pty Ltd.tr5](#)

Hi s22

Thank you for your time on the phone. As discussed, the sponsor - Boston Scientific Pty Ltd, has provided a response ([D17-943964](#)) to your Round 2 Clinical assessment for the NG4 s22 and Momentum (details below).

Please find attached the Round 3 Clinical Assessment form ([D17-944425](#)). I have updated WM as well.

Also, please note that I have now returned the applications to the sponsor for them to amend the intended purpose as requested.

Device UPI:	s22 MOMENTUM CRT-D - G125 s22
Sponsor:	Boston Scientific Pty Ltd
Manufacturer:	Cardiac Pacemakers Inc. (United States Of America)[9897]
Application ID:	s22 DV-2017-DA-02403-1 s22
Submission ID:	s22 DA-2017-01356-1, s22 s22
DAVS Assessor:	s22
Application TRIM	(E17-5437, E17-5438, E17-5442, E17-5445, E17-5443, E17-5446 E17-5451, E17-5448, E17-5450 1 st Data submission - D17-324877 2 nd Data submission - D17-705246
Sponsor's submission TRIM Ref.:	Sponsor's response to Rd 2 Clinical: TRIM: D17-943964 <ul style="list-style-type: none"> Addendum to CER Revised IFU
Date submitted to TGA:	10/11/2017
Date Referred to Clinical Section:	15/11/2017
Clinical Round:	3 Clinical screening report: D17-344962 1 st round of clinical assessment: D17-326283 2 nd round of clinical assessment: D17-701431

Kind regards

s22

s22

Devices Applications and Verification
Medical Devices Branch

Phone: s22

Email: s22 [@health.gov.au](mailto:s22@health.gov.au)

Therapeutic Goods Administration

Department of Health

PO Box 100

Woden ACT 2606 Australia

www.tga.gov.au



Medical Device Application

ARTG No : 296564

AIMD Status : Approved

Application Change history

E17-5438 (s22), 16/03/2017)
Correct TRIM E17-5442 (s22), 27/04/2017)

Application Progress Date

Date received: 21/11/2017

Review Information

Review flag: Returned from applicant review

Auto review required: No

Device Product Characteristics

Is the device, or any form of the device, supplied sterile: Yes
Is the device intended to be invasive: Yes
Is the device, or any form of the device, intended for single use: Yes
Is the device an active device: Yes
Does the device contain material or ingredients of microbial origin: No
Does the device contain material or ingredients of recombinant origin: No
Does the device contain material or ingredients manufactured or formulated using a genetically modified organism: No
Does the device contain material or ingredients of Human Origin: No
Does the device consist of: Single product only
Does the device contain material or ingredients of Animal Origin rendered non-viable: No
Is the device medicated: No
Does the product contain a medicine that is supplied separately in the Australian Market: No
Does the product contain a medical device which incorporates a medicine as an integral part and that has an action ancillary to the device: No

Application Summary

Application ID: DV-2017-DA-02403-1

Submission ID: DA-2017-01356-1

Sponsor's own reference: NG4 - MOMENTUM CRT-D - G125

Application for: Medical Device - Included

Will you be applying for listing of this product or procedure in ☐ Yes ☐ No

the Medicare Benefit Schedule (MBS)?

Will you be applying for listing of this product on the Prosthesis List? ☐ Yes ☐ No

Will you be applying for listing of this product on the Co-dependent or hybrid technology application list? ☐ Yes ☐ No

Sponsor name: Boston Scientific Pty Ltd

Sponsor ID: 23932

Agent name:

Contact details : s22

Contact email: s22 @bsci.com

Manufacturer Information

Manufacturer's evidence: DV-2014-MC-17490-1 :Annex II.3 St Paul Full Quality Assurance (CE 00027) Exp 17June2018 (Ingenio 2.0) [Goto](#)

Manufacturer name: Cardiac Pacemakers Inc (United States Of America)[9897]

Assessment route: Council Directive 90/385/EEC (AIMD)

Assessment body: BSI Product Services [0086]

GMDN code: Biventricular pacemaker/defibrillator[47270]

GMDN description: An implantable, battery-powered combination device consisting of a hermetically-sealed pacing pulse generator and an integrated defibrillation pulse generator with leads in the right ventricle, in a coronary vein over the left ventricle, and often in the right atrium (triple chamber). In addition to conventional pacing and defibrillation functions, the device provides cardiac resynchronization therapy (CRT) through biventricular electrical stimulation to synchronize right and left ventricular contractions for more effective blood pumping to treat symptoms of heart failure (e.g., shortness of breath, easy fatigue) and serious heart-rhythm problems.

Intended purpose : Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with heart failure who receive stable optimal pharmacologic therapy (OPT) for heart failure and who meet any one of the following classifications:

- Moderate to severe heart failure (NYHA Class III-IV) with EF $\leq$ 35% and QRS duration $\geq$ 120 ms
- Left bundle branch block (LBBB) with QRS duration $\geq$ 130 ms, EF $\leq$ 30%, and mild (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class I) ischemic heart failure.

Boston Scientific CRT-Ds are also intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

Device Category Terms

Product Details

UPI (Unique product identifier): MOMENTUM CRT-D - G125

Attached Documentation

-  Design Examination Certificate - CE663431 - DE certificate.pdf
-  Request for a reduction in application audit fees - Application for fee reduction - NG4 CRT-D and ICD devices.doc
-  Design Examination Certificate - CE663431 - DE certificate.pdf
-  Design Examination Certificate - CE663431 - DE certificate.pdf
-  EC Certificate - CE663431 - DE certificate.pdf

History

21/11/2017 3:02:56 PM Approved.
 Payment notification mail has been sent to PDC on 7/03/2017
 Review Completed - Accepted, 21/11/2017)

Record**Date**

Fee: 1290 Date Paid: 06/03/2017
 Date Decision: 21/11/2017

Start Dates**Finish Dates****Working Days**

Application Received	21/11/2017	Payment Received	06/03/2017	0
Total Working Days				4



Australian Government
Department of Health
 Therapeutic Goods Administration

TGA use only

This form is classified 'For official use only'.

For guidance on how to treat information : see <<http://www.tga.gov.au/about/tga-information-to.htm>>.

Application Audit Checklist (Level 2)

Submission ID:	DA-2017-01356-1
Application ID:	DV-2017-DA-02403-1
TRIM Reference:	E17-5442

Sponsor Name:	Boston Scientific Pty Ltd
Manufacturer Name:	Cardiac Pacemakers Inc (United States Of America)[9897]
UPI:	MOMENTUM CRT-D - G125
Classification:	AIMD
GMDN Term & Code:	Biventricular pacemaker/defibrillator[47270]

OUTCOME OF THE ASSESSMENT/RECOMMENDATION: INCLUDE KIND OF DEVICE IN ARTG

Description of the kind of device (please include images and references to the relevant documents if required):

This application is for a cardiac resynchronization therapy defibrillator - MOMENTUM CRT-D - G125. This Device belongs to the NG4 family of devices that represents Boston Scientific's latest generation of implantable cardioverter defibrillator (ICD) and CRT-devices.

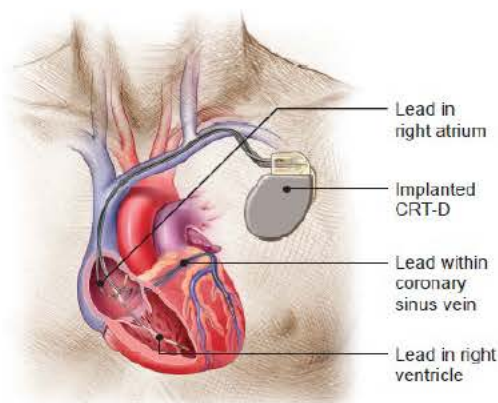


Figure 8. An implanted CRT-D system.

(page 28, [D17-346153](#) – Patient Handbook)

Functional Description as per Device application:

MOMENTUM CRT-D provides ventricular tachyarrhythmia therapy, cardiac resynchronization therapy and bradycardia pacing through a range of low- and high-energy shocks using a biphasic waveform; and a choice of multiple shock vectors.

This is consistent with Device therapies described in the IFU (page5/98, [D17-227847](#)).

This Device is not claiming MR Conditional (page43/98, [D17-227847](#)).

This application is associated with 8 other ICD/CRT-D Devices applications that have been grouped together for clinical assessment ([D17-326283](#)):

Submission ID	Application ID	Description	Model Number	Chamber	MR Conditional
s22	s22	s22	s22	s22	s22
DA-2017-01356-1	DV-2017-DA-02403-1	Momentum	G125	CRT-D	No
s22	s22	s22	s22	s22	s22

Boston Scientific's predicate generation of [s22](#)/CRT-D Devices, known as NG3, were included in the ARTG in 2014:

CRT/D – ARTG#s 221615, 221616, 221617, 221618, 221619, 221620, 221621, 221622, 221623, 221624, 221625, 221626, 221633

[s22](#)

GENERAL INFORMATION	
Application was selected for audit ¹	☒ YES ☐ NO If 'YES': ☒ s.41FH(1)(a) ☐ s.41FH(1)(b)
Date of s.41FH selection notice	23/03/2017 D17-234087

Part 1 –Application

Information provided in the application - Manufacturer's Evidence	
1.1 Manufacturer's Evidence ID:	DV-2014-MC-17490-1
<ul style="list-style-type: none"> Certificate issued by Notified body 	Certificate#: CE 00027
<ul style="list-style-type: none"> Notified Body name and ID: 	BSI Product Services [0086]
EC Certificate	Certificate#: CE

¹ Click on the check box to indicate the answer

Information provided in the application - Manufacturer's Evidence	
<ul style="list-style-type: none"> - Full Quality Assurance system - Directive 90/385/EEC - AIMD - Scope covers Device <p>EC Certificate - Full Quality Assurance Directive 90/385/EEC on Medical Devices, Annex 2, excluding Section 4</p> <p>No. CE 00027 Issued To: Cardiac Pacemakers Inc a wholly owned subsidiary of Guidant Corporation a wholly owned subsidiary of Boston Scientific Corporation 4100 Hamline Avenue North St. Paul Minnesota 55112-5798 USA</p> <p>In respect of: The design, development, manufacture and sterilisation of implantable cardiac pulse generators, implantable cardioverter defibrillators, implantable cardiac pacing and defibrillation leads, balloon catheters and guidewires, external instrumentation and accessories.</p>	00027, Annex 2 excluding (4) Expiry date: 17/06/2018

Information provided in and with the application	Yes	No	NA ²
1.2 Is application effective?	☒	☐	☐
<ul style="list-style-type: none"> • <u>Is application made in accordance with subsection 41FC(1) of the TG Act (i.e. in accordance with the form and manner approved)?</u> 	☒	☐	☐
<ul style="list-style-type: none"> • <u>Is this medical device one of the kind specified under MD Regulation 4.1 made for the purposes of section 41EA that requires the manufacturer to have a TGA conformity assessment certificate before an application for inclusion of that device in ARTG can be made, and no such certificate is in force?</u> 	☐	☒	☐
<ul style="list-style-type: none"> • <u>Does the application contain information that is false or misleading in a material particular (e.g. fraud certificate)?</u> – Not to my knowledge. 	☐	☒	☐
1.3 Was application made for a kind of device?	☒	☐	☐
<ul style="list-style-type: none"> • <u>Is the device nomenclature system codes (GMDN) the relevant preferred term/collective term for the devices of the kind (Regulation 1.7)?</u> – Biventricular pacemaker/defibrillator[47270] <ul style="list-style-type: none"> ○ An implantable, battery-powered combination device consisting of a hermetically-sealed pacing pulse generator and an integrated defibrillation pulse generator with leads in the right ventricle, in a coronary vein over the left ventricle, and often in the right atrium (triple chamber). In addition to conventional pacing and defibrillation functions, the device provides cardiac resynchronization therapy (CRT) through biventricular electrical stimulation to synchronize right and left ventricular contractions for more effective blood pumping to treat symptoms of heart failure (e.g., shortness of breath, easy fatigue) and serious heart-rhythm problems. – GMDN is current. – GMDN is consistent with DoC (D17-324877 - NG4 - G124, G125, G126, G128, G447 - CRT-D Doc). 	☒	☐	☐
<ul style="list-style-type: none"> • <u>For Class III, AIMD and Class 4IVD, does the unique product identifier (UPI) stated in the application accurately identify the devices of the kind?</u> 	☐	☐	☐

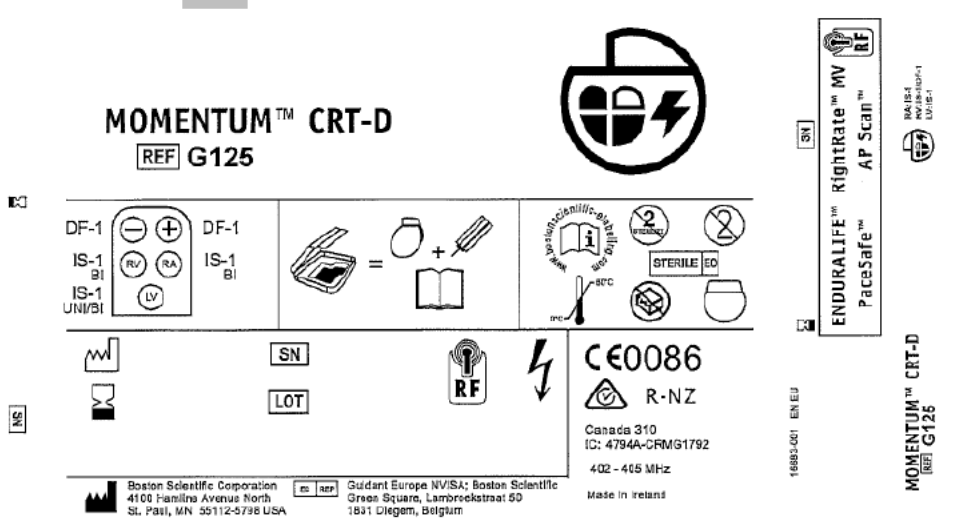
² NA means - 'Not applicable' and/or 'Not enough information to be assessed'

Information provided in and with the application	Yes	No	NA ²																								
<ul style="list-style-type: none"> Based on the Device application, UPI is: <ul style="list-style-type: none"> MOMENTUM CRT-D - G125 This is consistent with: <ul style="list-style-type: none"> DoC (D17-324877 - s22, G125, s22 DE Certificate (D17-188355), IFU (D17-227847, page 43/98), Labelling (page 2/4, D17-324877 - Appendix B - labels - s22, G125, s22 																											
<ul style="list-style-type: none"> <u>For Class III, AIMD and Class 4IVD, are the variants and total number of devices stated in the application correct according to the information provided?</u> <ul style="list-style-type: none"> Number of Devices: 1 Variant: NIL This is consistent with: <ul style="list-style-type: none"> DoC (D17-324877 - s22, G125, s22 DE Certificate (D17-188355), IFU (D17-227847, page 43/98), <p><u>As per Device application:</u></p> <table border="1"> <thead> <tr> <th colspan="3">Product Details</th> </tr> </thead> <tbody> <tr> <td colspan="3">UPI (Unique product identifier): MOMENTUM CRT-D - G125</td> </tr> <tr> <td>Total number of devices covered:</td> <td colspan="2">1</td> </tr> </tbody> </table> <table border="1"> <thead> <tr> <th colspan="3">Variant List</th> </tr> <tr> <th>#</th> <th>Variant type</th> <th>Variant range</th> </tr> </thead> <tbody> <tr> <td>1.</td> <td>NIL variant (as 1 device)</td> <td>N/A</td> </tr> </tbody> </table> <p><u>As per DoC</u> Medical device(s): s22</p> <p>MOMENTUM CRT-D G125</p> <p>s22</p> <p><u>As per DE:</u></p> <table border="1"> <thead> <tr> <th>MOMENTUM™ CRT-D Models</th> <th>s22</th> <th>G125, s22</th> </tr> </thead> <tbody> <tr> <td>s22</td> <td>s22</td> <td>s22</td> </tr> </tbody> </table>	Product Details			UPI (Unique product identifier): MOMENTUM CRT-D - G125			Total number of devices covered:	1		Variant List			#	Variant type	Variant range	1.	NIL variant (as 1 device)	N/A	MOMENTUM™ CRT-D Models	s22	G125, s22	s22	s22	s22	☒	☒	☐
Product Details																											
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MOMENTUM™ CRT-D Models	s22	G125, s22																									
s22	s22	s22																									
1.4 Was <u>any other</u> information provided <u>with the application</u> ?	☒	☐	☐																								
<ul style="list-style-type: none"> <u>Certificate (e.g. Design-Examination Certificate or Type Examination Certificate Certificates appropriate for Class III/AIMD device)</u> <p><u>Full Quality Assurance System:</u></p> <ul style="list-style-type: none"> Certificate Number: Certificate#: CE 00027, Annex 2 excluding (4) Issued by BSI Product Services [0086] in accordance with Directive 90/385/EEC Annex 2 excluding section (4) Expiry date: 17/06/2018 <p><u>EC Design Examination Certificate:</u></p> <ul style="list-style-type: none"> Certificate number: CE 663431 (D17-188355), Issued by BSI Product Services [0086] in accordance with Directive 90/385/EEC Annex 2 (4) Expiry date: 10.01.2022 	☒	☐	☐																								
<ul style="list-style-type: none"> <u>Declaration of Conformity</u> <ul style="list-style-type: none"> Ref: D17-324877 - s22, G125, s22 	☒	☐	☐																								
<ul style="list-style-type: none"> <u>Labelling for the medical device</u> 	☒	☐	☐																								

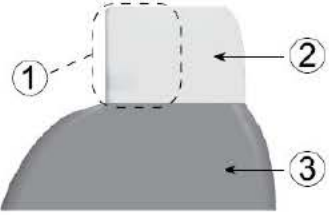
Information provided in and with the application		Yes	No	NA ²
<ul style="list-style-type: none"> Ref: page 2/4, D17-324877 – Appendix B – labels – s22 G125, s22 				
<ul style="list-style-type: none"> <u>Instructions for use (IFU)</u> Ref: D17-227847 Ref: D17-324877 – Appendix C - MRI Tech Guide RevA7 Ref: D17-324877 – Appendix C - Patient ID card Ref: D17-346153 – Patient Handbook 		☒	☐	☐
<ul style="list-style-type: none"> <u>Any other information (e.g. data from the National Joint Replacement Registry)</u> 		☐	☐	☒
1.5	<p>Is there any other information/device characteristics that need to be considered in the application (e.g. the device is a procedure pack/sterile/active, etc)?</p> <ul style="list-style-type: none"> Sterile – EO, invasive, active – AIMD, single use. Single product – device is packaged with 1 torque wrench and IFU (D17-227847, page 44/98). 	☒	☐	☐
1.6	<p>Are there any known concerns about the device (specifically or in general, e.g. the device is a vaginal mesh or EC Certificate was issued by one of the Notified bodies of concern)</p> <ul style="list-style-type: none"> Not to my knowledge. 	☐	☒	☐

Part 2 –Audit Assessment

Are certifications made under section 41FD of the <i>Therapeutic Goods Act 1989</i> correct in relation to the kind of device?		Yes	No	NA
2.1	Paragraph 41FD(a) – Is product in the application a medical device according to section 41BD of the Act?	☒	☐	☐
2.2	<p>Paragraph 41FD(b) – Are devices of the kind intended to be used for a purpose as ascertained under subsection 41BD(2)?</p> <ul style="list-style-type: none"> <u>Is the intended purpose stated in the application correct according to the information provided with the device?</u> <p>As per Device application:</p> <p><i>Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with heart failure who receive stable optimal pharmacologic therapy (OPT) for heart failure and who meet any one of the following classifications:</i></p> <ul style="list-style-type: none"> <i>Moderate to severe heart failure (NYHA Class III-IV) with EF ≤ 35% and QRS duration ≥ 120 ms</i> <i>Left bundle branch block (LBBB) with QRS duration ≥ 130 ms, EF ≤ 30%, and mild (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class I) ischemic heart failure.</i> <p><i>Boston Scientific CRT-Ds are also intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.</i></p> <ul style="list-style-type: none"> This is consistent with the CER (D17-324877 - Clinical Data Summary Report page 23/388) and IFU (D17-227847, page 9/98). <p>Note: the IP was amended to be consistent with the predicate device; amended application (D17-948980), original application (D17-215576).</p>	☒	☐	☐

Are certifications made under section 41FD of the <i>Therapeutic Goods Act 1989</i> correct in relation to the kind of device?	Yes	No	NA
<p>2.3 Paragraph 41FD(c) – Is the kind of device correctly classified according to the medical device classifications (medical devices are classified based on its intended purpose, refer Division 3.1 and Schedule 2 or Schedule 2A for IVD of MD Regulations)?</p> <ul style="list-style-type: none"> – Class AIMD – Classification Rule 5.7(1) of Schedule 2 of the Therapeutic Goods (Medical Devices) Regulations 2002. 	☒	☐	☐
<p>2.4 Paragraphs 41FD(d) and (e) – Essential Principles (Schedule 1 of the MD Regulations)</p> <ul style="list-style-type: none"> • Paragraphs 41FD(d) – Are devices of the kind comply with the essential principles? • Paragraphs 41FD(e) – Does the applicant have available sufficient information to substantiate compliance or have procedures in place, including a written agreement with the manufacturer, to ensure that information can be obtained within the period specified in the regulations? 	☒	☐	☐
<p>- Essential Principle 13</p> <ul style="list-style-type: none"> - EP13.1 – compliant <ul style="list-style-type: none"> o Package labels provided. o IFUs provided with device. - EP13.2 – compliant with subclause 2 and subclause 4 - EP13.3 – Labels compliant <ul style="list-style-type: none"> o Ref: page 2/4, D17-324877 – Appendix B – labels – s22, G125, s22 <div style="text-align: center;">  </div> <ul style="list-style-type: none"> - EP13.4 – IFUs compliant <ul style="list-style-type: none"> o Ref: D17-227847 o Ref: D17-324877 – Appendix C - MRI Tech Guide RevA7 o Ref: D17-324877 – Appendix C - Patient ID card o Ref: D17-346153 – Patient Handbook o Manufacturer's name and address consistent with the EC certificate. o Sterilised using EO consistent with IFU. 	☒	☐	☐

Are certifications made under section 41FD of the <i>Therapeutic Goods Act 1989</i> correct in relation to the kind of device?	Yes	No	NA
<ul style="list-style-type: none"> • <u>Regulation 10.2</u> <ul style="list-style-type: none"> – AUS sponsor is included at the back of D17-324877 – Appendix C - MRI Tech Guide RevA7 and D17-346153 – Patient Handbook <div style="border: 1px solid black; padding: 5px; margin: 10px 0;"> AUS </div> <p>Boston Scientific (Australia) Pty Ltd PO Box 332 BOTANY NSW 1455 Australia Free Phone 1 800 676 133 Free Fax 1 800 836 666</p>	☒	☐	☐
<ul style="list-style-type: none"> • <u>Essential Principle 14 (and conformance with Part 8 of Schedule 3)</u> <ul style="list-style-type: none"> – CER provided (D17-324877 - Clinical Data Summary Report) – Initial clinical assessment (D17-344962) = Completed, beyond scope <ul style="list-style-type: none"> ○ <i>It is unclear if all the Devices covered in this application have been approved by FDA and under what conditions eg MR safety, indications etc. This needs to be clarified.</i> ○ <i>Clinical evidence submitted predominantly consist of literature data which appear generalised and non-specific at this initial assessment; multiple claims of substantial equivalence of the subject Devices and multiple predicate devices and a comparator device; and post-market data that were not specific to the predicate devices alone with adverse event/complaint rate data provided without a clear analysis. A further more detailed assessment is required. It is likely that a significant amount of time would be needed for in particular the assessment of the equivalence claims; the post-market data of the predicate/comparator devices; and the MRI safety for each individual Device and its labelling requirements.</i> – Rd 1 Clinical assessment (D17-326283) = No, further information required <ul style="list-style-type: none"> ○ s41JA Notice sent (D17-563229) – Sponsor response (D17-701387) – Rd 2 Clinical assessment (D17-701431) = No, <ul style="list-style-type: none"> ○ IP in application, IFU and CER for CRT-D devices to be amended to be consistent with predicate Device ○ s41JA Notice sent (D17-811192) – Sponsor response (D17-943964) and amended application (D17-948830) – Rd 3 Clinical assessment (D17-944425) = YES 	☒	☐	☐
<ul style="list-style-type: none"> • <u>Essential Principles – Part 1 of Schedule 1 - a risk management report</u> <ul style="list-style-type: none"> – Risk management documents provided (D17-324877 – Appendix F – Risk Analysis) – Initial clinical assessment (D17-344962) = Completed, beyond scope – Rd 1 Clinical assessment (D17-326283) = No, further information required <ul style="list-style-type: none"> ○ s41JA Notice sent (D17-563229) – Sponsor response (D17-701387) – Rd 2 Clinical assessment (D17-701431) = Overall No but Yes for risk management <ul style="list-style-type: none"> ○ s41JA Notice sent (D17-811192) – Sponsor response (D17-943964) and amended application (D17-948830) – Rd 3 Clinical assessment (D17-944425) = YES 	☒	☐	☐

Are certifications made under section 41FD of the <i>Therapeutic Goods Act 1989</i> correct in relation to the kind of device?	Yes	No	NA
<ul style="list-style-type: none"> <u>Essential Principle - other</u> <p>EP12.13 – X-ray Identifier As per page 51/98 IFU (D17-227847):</p> <p>X-RAY IDENTIFIER</p> <p>The pulse generator has an identifier that is visible on x-ray film or under fluoroscopy. This identifier provides noninvasive confirmation of the manufacturer and consists of the following:</p> <ul style="list-style-type: none"> s22 MOMENTUM pulse generators, the letters BSC identify Boston Scientific as the manufacturer. The number 140 identifies the Model 2868 PRM software application needed to communicate with the pulse generator. <p>The x-ray identifier is embedded in the header of the device. For a left side pectoral implant, the identifier will be visible by x-ray or fluorography at the approximate location shown (Figure 1 X-ray Identifier on page 48).</p>  <p>[1] X-Ray Identifier [2] Header [3] Pulse Generator Case</p> <p>Figure 1. X-ray identifier</p>	☒	☐	☐
<p>2.5 Paragraphs 41FD(f) and (g) – conformity assessment procedures</p> <ul style="list-style-type: none"> Paragraphs 41FD(f) – Has the appropriate conformity assessment procedure been applied to the kind of device? Paragraphs 41FD(e) – Does the applicant have available sufficient information to substantiate the application of the conformity assessment procedures or have procedures in place, including a written agreement with the manufacturer of the kind of device, to ensure that information can be obtained from the manufacturer within the period specified in the regulations? 	☒	☐	☐
<ul style="list-style-type: none"> Is the device in the application a medical device used for a special purpose (according to Regulation 3.10) (e.g. procedure pack)? 	☐	☒	☐

Are certifications made under section 41FD of the <i>Therapeutic Goods Act 1989</i> correct in relation to the kind of device?	Yes	No	NA								
<ul style="list-style-type: none"> Provide information about conformity assessment procedure that has been applied to the kind of device <p>DE Certificate (D17-188355)</p> <ul style="list-style-type: none"> Certificate#: CE 663431 Directive 90/385/EEC – AIMD, Annex 2(4) Expiry: 10.01.2022 Scope covers device <p>EC Design-Examination Certificate <small>Directive 90/385/EEC on Active Implantable Medical Devices, Annex 2 Section 4</small></p> <p>No. CE 663431 Issued To: Cardiac Pacemakers, Incorporated a wholly owned subsidiary of Guidant Corporation a wholly owned subsidiary of Boston Scientific Corporation 4100 Hamline Avenue North St Paul Minnesota 55112-5798 USA</p> <p>In respect of: NG4 Family of Pulse Generators</p> <table border="1"> <tr> <td>MOMENTUM™ CRT-D Models</td> <td>s22</td> <td>G125,</td> <td>s22</td> </tr> <tr> <td>s22</td> <td>s22</td> <td></td> <td></td> </tr> </table> <p>EC certificate</p> <ul style="list-style-type: none"> See section 1 Scope covers device Certificate Number: Certificate#: CE 00027 Directive 90/385/EEC Annex 2 excluding section (4) Expiry date: 17/06/2018 	MOMENTUM™ CRT-D Models	s22	G125,	s22	s22	s22					
MOMENTUM™ CRT-D Models	s22	G125,	s22								
s22	s22										
<ul style="list-style-type: none"> Does the procedure meet the minimum requirements that must be applied to the device of this classification according to Division 3.2 (if the kind of device in the application is not a device to be used for a special purpose, refer MD Regulations 3.6 – 3.9B and Schedule 3 of the MD Regulations; for the device used for a special purpose – refer Part 7 of Schedule 3 of the MD Regulations). 	☒	☐	☐								

Are certifications made under section 41FD of the <i>Therapeutic Goods Act 1989</i> correct in relation to the kind of device?	Yes	No	NA
<ul style="list-style-type: none"> Has <u>declaration of conformity (DoC)</u> been made in accordance with Schedule 3 of MD Regulations? <ul style="list-style-type: none"> Ref: D17-324877 - s22, G125, s22 DoC is made in accordance with Clause 1.8 of Schedule 3 of the Regulations <p style="text-align: center;">MANUFACTURER'S DECLARATION OF CONFORMITY</p> <p style="text-align: center;"><i>AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002</i></p> <p style="text-align: center;">FULL QUALITY ASSURANCE PROCEDURES</p> <p>This is a declaration of conformity made under clause 1.8 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.</p> <ul style="list-style-type: none"> UPI, manufacturer's name/address and GMDN code (47270) are consistent with Application. EC and DE certificate numbers are reference correctly. Includes a list of standards and products. <p>Authorised signatory:</p> <p>s22</p> <p style="text-align: right;"><i>4 March 2017</i></p> <p style="text-align: right;">Date</p> <p>Manager Regulatory Affairs 01 March 2017</p>	☒	☐	☐
2.6 Paragraphs 41FD(h) – Does the submitted information demonstrate compliance with the applicable provisions of the Therapeutic Goods Advertising Code and other requirements (if any) relating to advertising? Note: if advertising is only aimed at health professionals these requirements are not applicable.	☐	☐	☒
2.7 Paragraphs 41FD(i) – Do devices of the kind contain substances that are prohibited imports under the Customs Act 1901? <ul style="list-style-type: none"> Not to my knowledge 	☐	☒	☐
2.8 Paragraphs 41FD(ja) – FOR IVD only - Are devices of that kind intended to be used exclusively for one or more of the purposes specified under section 41BEA?	☐	☐	☒
2.9 Paragraphs 41FD(j) – Is the information included in and with the application complete and correct?	☐	☐	☐

Part 3 –Audit Assessment

Is there anything else relevant to the assessment of the application?	Yes	No	NA
2.10 Has all information been provided?	☒	☐	☐
2.11 Are there any other information/concerns that need to be considered/assessed?	☐	☒	☐

Additional comments (if required)

Signed and authorised by	Position number:	NA / Contractor
Assessor's name: s22	Date	17/11/2017

Delegate's checklist	
Do you have delegation for the purposes of section 41FI of the Act (or under section 41FF if application is finalised without the audit)?	☒ Yes ☐ No
Have you checked that all requirements set out under section 41FI (or section 41FF if application is finalised without the audit) have been considered and met in making this decision?	☒ Yes ☐ No
Specify other if required:	☐ Yes ☒ No

Delegate's decision	
REQUIRE FURTHER INFORMATION under section 41JA of the Act	☐ Yes ☒ No
INCLUDE KIND OF DEVICE IN ARTG	☒ Yes ☐ No
IMPOSE CONDITIONS under section 41FO of the Act	☐ Yes ☒ No
Other: section 41FL and subsection 41FJ(a)	☒ Yes ☐ No

Comments (if required)

Audit has been conducted in relation to the following matters:

- (a) whether the application is in accordance with Subdivision A; and
- (b) whether matters as to which the applicant has certified under section 41FD are correct.

Following consideration of the information provided, I am satisfied to all aspects considered during the audit and endorse the assessor's recommendation.

Therefore, as a delegate of the Secretary of the Department of Health for the purposes of subsection 41FI(2) of the *Therapeutic Goods Act 1989* I have made a decision to include the kind of device in the ARTG.

Delegate's name:	s22	Position number:	s22
Signature	Signed electronically	Date	21 November 2017



Australian Government
Department of Health
Therapeutic Goods Administration

Application Audit – Level 2 (compulsory/non-compulsory) *Initial Clinical Assessment (Triage) report*

TRIM Reference: [D17-344962](#)

Application ID(s):	s22 , DV-2017-DA-02403-1 s22
Submission ID:	s22 DA-2017-01356-1, s22 s22
Applicant's submission:	TRIM: D17-324877 <ul style="list-style-type: none"> Appendix H - DE Certificate Appendix G - MRI Interaction Appendix F - Risk Analysis Appendix E - Clinical Experience Summary Appendix C - IFUs Appendix B - Labels Appendix A - Predicate ARTGs Cover Letter.pdf <p>CER and CV – saved in Appendix E – Clinical Experience Summary Risk Analysis – saved on Appendix F – Risk Analysis Labels and IFU and Predicate – saved in Appendix C, B and A. (IFU and Labels are identified via the model numbers) Cover letter</p>
Sponsor:	Boston Scientific Pty Ltd
Manufacturer:	Cardiac Pacemakers Inc (United States Of America)[9897]

The Device(s)

1.	Unique Product Identifier(s)	s22 MOMENTUM CRT-D - G125, s22
2.	GMDN code and term	Biventricular pacemaker/defibrillator[47270] - s22 s22 MOMENTUM CRT-D - G125, s22 s22

		s22
3.	The description of the Device(s) (if required)	s22 MOMENTUM CRT-D - G125, s22 G447 – Page 1-4 s22
4.	General specialty category the Device(s) belongs to ¹	☐ Anaesthesiology ² ☒ Cardiovascular ☐ Ear, Nose, and Throat ☐ Gastroenterology and Urology ☐ Plastic Surgery ☐ Immunology ☐ Neurology ☐ Obstetrical and Gynaecological ☐ Ophthalmic ☐ Orthopaedic ☐ Radiology ☐ None of the above, specify:
5.	Is the device:	☒ AIMD ☐ Passive implantable device ☐ Surgically invasive medical devices intended for long-term use ☐ None of the above
6.	The intended purpose(s) ³	As per the Application: s22 MOMENTUM CRT-D - G125, s22 - This device is indicated for patients who are at risk for sudden cardiac death caused by ventricular arrhythmias and who have heart failure (including asymptomatic [NYHA Class I] ischemic heart failure) with ventricular dyssynchrony. s22

¹ Examples of the Device Classification Panels, credit to the US FDA website:
<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051530.htm>.

² Refer the 'Clinical evidence guidelines: Medical devices' for the requirements for specific categories of medical devices: <https://www.tga.gov.au/publication/clinical-evidence-guidelines-medical-devices>

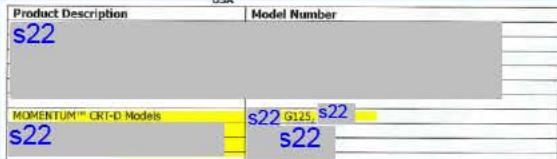
³ Essential principle 14 of Schedule 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002*: Every medical device requires clinical evidence, appropriate for the use and classification of the device, demonstrating that the device complies with the applicable provisions of the essential principles.

		<p><i>treatment of life-threatening ventricular arrhythmias.</i></p> <p>As per the information provided with the Device (s) (e.g. IFU):</p> <p>NOTE – The IFU are separated and titled by the model numbers</p>
7.	Indications for the use of the Device(s)	<p>s22</p> <p>MOMENTUM CRT-D - G125, s22</p> <p>Boston Scientific implantable cardioverter defibrillators (ICDs) are intended to provide ventricular antitachycardia pacing (ATP) and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. – PTM – s22, G125 s22</p> <p>Page 9</p> <p>s22</p> <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p>
8.	Is the Device an existing or novel technology?	<p>☒ Existing ☐ Novel</p> <p>Comment if required:</p>
9.	Is the Device intended to be used as a component/part of the system (e.g. pacemaker and leads or component of a joint replacement system)	<p>☒ YES ☐ NO (IF 'NO' GO TO Paragraph 11)</p> <p>Comment if required: <u>the Devices accept multiple different leads depending on the model.</u></p>
10.	Have the other devices from the same system been already included in the ARTG?	<p>☐ YES ☒ NO</p> <p>Comment if required: <u>The Devices work with multiple different leads depends on the model. It is not practical to review data for each and individual system. Devices would be assessed on its own.</u></p>
11.	Are there any known predicate device(s) included in the ARTG (e.g. from the same family of devices)	<p>☒ YES ☐ NO</p> <p>Comment if required: Provided by sponsor – ARTG Cert – Appendix A – Predicate ARTGs</p> <p>[Redacted]</p> <p><u>Boston Scientific (BSC) requests approval for new NG4</u></p>

		s22
12.	Is there the same device included by a different sponsor?	☐ YES ☒ NO Comment if required: Search Based on GMDN code and manufacturer – no device found - ARTG
13.	Is there any other information that can assist in assessing this particular Application?	☐ YES ☒ NO Comment if required:

The regulatory history of the Device(s) in other countries

Please include approval number(s) if known and reference(s)/link(s) to where this information is available

14.	EC Certificate (Notified Body, date of issue and the scope)	<p>EC DE Certificate – CE 663431 – under Directive 90/385/EEC on active implantable medical devices, Annex 2 section 4 for NG4 Family of Pulse Generators – expiry – 10/01/2022, issued 11 January 2017</p> 
15.	Has the Device been approved by the US FDA (PMA or 510K)?	<p>☐ YES ☐ NO ☒ Not known</p> <p>Comment if required: Not clear if the devices in this application are covered under PMA below:</p> <p>PMA Number – P960040 – issued on 17/4/17</p>  <p>PMA Number – P010012 – Issued on 17/4/17.</p>

	<div style="border: 1px solid black; padding: 5px;"> <p style="text-align: center;">New Search Back to Search Results</p> <p>Note: This medical device record is a supplement. The device description may have changed. Be sure to look at the previous PMAs to get an up-to-date view of this device.</p> <p>Device: COGUS, ENERGEN, PUNCTUA, INCEPTA, ORIGIN, NOOGEN, DYNAGEN, AUTOGEN, RESONATE, MOMENTUM, VISUALANT CRT-2's Resynchroniza</p> <p>Classification Name: Defibrillator, Automatic Implantable Cardioverter, With Cardiac Resynchronization (CPRD)</p> <p>Generic Name: Defibrillator, automatic implantable Cardioverter, With Cardiac Resynchronization (CPRD)</p> <p>Applicant: Osceon Scientific Corp. 4100 Hamline Ave North St. Paul, MN 55112</p> <p>PMA Number: P010012</p> <p>Supplement Number: S438</p> <p>Date Received: 10/02/2016</p> <p>Decision Date: 04/17/2017</p> <p>Product Code: NKK [Supplemental Establishment With NKK]</p> <p>Advisory Committee: Cardiovascular</p> <p>Supplement Type: Normal 180 Day Track</p> <p>Supplement Reason: Change Design/Components/Specifications/Material</p> <p>Expedited Review Granted? No</p> <p>Combination Product: No</p> <p>Approval Order Statement: Approval for the LATITUDE NXT Patient Management System Release 5.0</p> </div>
16. Has the Device been approved by the Health Canada	☐ YES ☒ NO ☐ Not known Comment if required: Device was not located on register after search.
17. Has the Device been approved in Japan	☐ YES ☐ NO ☒ Not known Comment if required:

The clinical evidence provided by the applicant

18. Has a Clinical Evaluation Report (CER) been provided ⁴	☒ YES ☐ NO Appendix E - Clinical Data Summary Report.pdf
19. Has the CER been dated?	☒ YES ☐ NO Version G
20. Does the CER provide up-to-date information (i.e. it is dated within the last two years)?	☒ YES ☐ NO Comment if required: The CER is dated 25/09/2016.

⁴ Clause 8.4(1)(c) of Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002*: a written report by an expert in the relevant field, being a report that contains a critical evaluation of all the clinical investigation data held in relation to the device.

	<table border="1"> <tr> <th>Section of Document</th> <th>Authored By</th> <th>Approved By</th> </tr> <tr> <td>Device overview NDA Review Equivalence Evaluation</td> <td>Markus Stauder Principal Regulatory Affairs Specialist</td> <td></td> </tr> <tr> <td></td> <td>Xia Wang Principal Regulatory Affairs Specialist</td> <td>Dr. Hui Gao Sr. Medical Director</td> </tr> <tr> <td>USDA Review Equivalence Evaluation Clinical Studies Literature Review</td> <td>Vincent Lopez-Botero Sr. Clinical Trial Specialist</td> <td></td> </tr> <tr> <td>Market Experience</td> <td>Hadi Qader Sr. Product Performance Engineer</td> <td>Charles Krueger Director Quality Systems</td> </tr> <tr> <td>Harvard Risk Analysis</td> <td>James Dwyer E.A. D. Fellow</td> <td>John Keigley Director Quality Assurance</td> </tr> </table> <p>Approvers' electronic signatures, signatures dates, and document revision history are available in BIC's document management system.</p> <p>This Evaluation of Clinical Data summary worksheet submitted to us only by officials from BIC or other Regulatory Agencies who participate in the review of PCT/CTD devices. The document should be submitted in a secure location and should not be copied or made available for review by any unauthorized person or firm.</p>	Section of Document	Authored By	Approved By	Device overview NDA Review Equivalence Evaluation	Markus Stauder Principal Regulatory Affairs Specialist			Xia Wang Principal Regulatory Affairs Specialist	Dr. Hui Gao Sr. Medical Director	USDA Review Equivalence Evaluation Clinical Studies Literature Review	Vincent Lopez-Botero Sr. Clinical Trial Specialist		Market Experience	Hadi Qader Sr. Product Performance Engineer	Charles Krueger Director Quality Systems	Harvard Risk Analysis	James Dwyer E.A. D. Fellow	John Keigley Director Quality Assurance	
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Market Experience	Hadi Qader Sr. Product Performance Engineer	Charles Krueger Director Quality Systems																		
Harvard Risk Analysis	James Dwyer E.A. D. Fellow	John Keigley Director Quality Assurance																		
21. Has the clinical data been evaluated by competent clinical experts	☒ YES ☐ NO Comment if required: See question 20	We will can request the electronic signature page from sponsor.																		
22. Has CV been provided to demonstrate the competency of the clinical expert ⁵ ?	☒ YES ☐ NO s22																			
23. Has the CER been signed/endorsed by the clinical expert?	☒ YES ☐ NO Comment if required: See question 22 however a signature page is required see question 20																			
24. What is the form of the clinical evidence provided ⁶ ?	☐ Clinical investigation data ☒ Literature review ☐ Both																			
25. How the clinical evidence was provided?	☐ Direct data for the Device(s) ☒ Clinical evidence for the predicate(s)/comparator(s) ☐ Both																			
26. Has a comparative table between the Device and the claimed predicate/comparator device(s) and/or explanation to demonstrate substantial	☒ YES ☐ NO ☐ N/A Comment if required: Equivalence evaluation – Page 56 -91 <i>Claiming equivalence of the Devices with</i> <i>1) NG3 devices and 2) s22</i> <i>Due to the established device equivalence between the multi-site</i>																			

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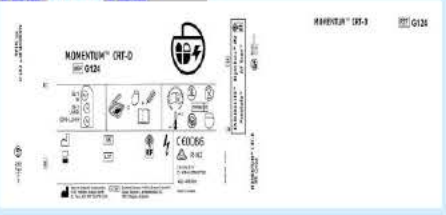
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⁵ Clause 8.6(1) of Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002*: The manufacturer of a kind of medical device must ensure that the clinical data is evaluated by competent clinical experts.

⁶ Clauses 8.3(1)(a) and 8.4 of Schedule 3: The manufacturer of a kind of medical device must obtain clinical data in relation to the device in the form of either or both of the following: (a) clinical investigation data; (b) a literature review.

	clinical equivalence been provided?	<i>pacing technology as well as equivalence between BSC's NG4 CRT-Ds and STJ's <u>s22</u> CRT-Ds, the clinical data on STJ's MSP is highly relevant to support the safety and performance of MSP in NG4 devices. This clinical data is presented and discussed in Section 5. Additionally, BSC clinical data from RALLY X4 and NAVIGATE X4 data further support the equivalence of BSC's MSP and STJ's MPP features, as discussed in Section 4.2.3.1.</i>
27.	Has provided analysis sufficiently demonstrated substantial equivalence?	☐ YES ☐ NO ☐ N/A Comment if required: <u>unable to determine at initial assessment due to comparison with multiple devices for multiple subject Devices. This application is considered to be beyond the scope of triage for determination of compliance with the EPs.</u>
28.	Has any data from the clinical trial(s)/study for the Device and/or the claimed predicate(s)/comparator(s) been provided?	☒ YES ☐ NO ☐ N/A Comment if required: Clinical data information - See page 92 - 103 and 232 - 280
29.	What sort of clinical trial/study the data has been provided for?	☐ Randomised Control Trial ☐ Non-randomised cohort study ☐ Case-control study ☐ Single-arm (case-series); multi-site ☐ Single-arm (case-series); single-site ☐ None of the above Comment if required: <u>multiple data had been provided</u>
30.	Has any post-market data for the Device and/or the claimed predicate(s)/comparator(s) been provided?	☒ YES ☐ NO ☐ N/A Comment if required: Market Experience – Page 282 – 297 <i>This historical record provides retrospective evidence of what can be expected and anticipated regarding the ongoing performance and reliability of the ICD/CRT-D devices. <u>Some post-market data has been provided for the predicate devices but not the comparator device in the market experience section. Further detailed evaluation is required for further assessment</u></i>
31.	Are there any records of adverse events/complaints for the Device and/or the claimed predicate(s)/comparator(s)?	☒ YES ☐ NO ☐ N/A Comment if required:
32.	Has comparison adverse event/complaint rate analysis been provided?	☐ YES ☒ NO ☐ N/A Comment if required:
33.	Has the literature review been provided for the Device and/or the claimed predicate(s)/comparator(s)?	☐ The Device ☒ Predicate/Comparator ☒ Both ☐ N/A Comment if required: <u>appears to be general only without focus on relevant comparator or predicate devices.</u>

⁷ Clauses 8.3(1)(b) and 8.5 of Schedule 3: As above, Literature review.

34.	What sort of literature review has been provided?	☐ Published literature on the Device ☐ Published literature on the predicate and/or comparator device(s) ☐ Unpublished scientific literature ☒ General broad search on the Device Comment if required:								
35.	Does the CER claim MRI Safe or MRI Conditional status of the Device?	☒ YES ☐ NO ☐ N/A Comment if required: CER - Pages 31-32 MRI Conditional Labelling – Pages 144-166 Page 1 – Cover letter <table border="1" data-bbox="523 696 997 853"> <thead> <tr> <th>Application Identifier</th> <th>Submission Identifier</th> <th>Description</th> <th>MR Conditional</th> </tr> </thead> <tbody> <tr> <td>DA-2017-01402403-1</td> <td>DA-2017-01156-1</td> <td>REGA-MOMENTUM CRT 0 - G125</td> <td>No</td> </tr> </tbody> </table> <p><u>Based on the information some of the subject Devices were being claimed as MR conditional where as some were not. Detailed assessment is required to see if there is adequacy of evidence submitted for safety under MR conditional environments for each of the applicable Devices. This cannot be done at this stage.</u></p>	Application Identifier	Submission Identifier	Description	MR Conditional	DA-2017-01402403-1	DA-2017-01156-1	REGA-MOMENTUM CRT 0 - G125	No
Application Identifier	Submission Identifier	Description	MR Conditional							
DA-2017-01402403-1	DA-2017-01156-1	REGA-MOMENTUM CRT 0 - G125	No							
36.	Is the same indicated in the manufacturer's IFU and on the label?	☒ YES ☐ NO ☐ N/A Comment if required:  <p><u>s22, G125 s22</u></p>  <p><u>s22</u></p>								

		s22
37.	Does the IFU contain the expected MRI Safety statement?	☒ YES ☐ NO ☐ N/A Comment if required: PTM - s22, G125 s22 - Page 7 IFU s22
38.	Is an ASTM testing report provided?	☒ YES ☐ NO ☐ N/A Comment if required: Expand MRI Access for Patients with New and Existing ICDs and CRT-Ds - Enable MRI study - Saved in - Appendix E - Clinical Experience Summary Appendix G - MRI Interaction 1127933_MRIImageArtifactRpt-ImageReadyMRCCondExDefibSystRpt_RevA4.pdf 1127903_UnintendedStimAnalysisRpt_RevA6.pdf 1127815_CombinedFieldsDATRptImageReadyMRCCondExDefibSyst_RevA14.pdf 1127565_Tachy_MRI_MDVT_Report_RevC.pdf 1126865_EDVT MR Conditional NG3_RevB2.pdf 1102638_TachyMRI UsabilityEngSummaryRpt_A4.pdf 1102382_NG3 MRI EvalSummary_RevB2.pdf

Commented s22: Is this the study designation if so a comment of explanation would be in order.

39.	Does the risk analysis include tables to enlist possible risks and measures to manage those risks?	☒ YES ☐ NO ☐ Unknown Comment if required: Risk analysis report provided along with safety risk management process tables. Appendix F – Risk Analysis  Safety Risk Management Process.pdf  NG4 Safety Risk Management Report.pdf  HeartLogic - MSP Hazard Analysis Report.pdf  CRM MultiSENSE Safety Risk Management Plan.pdf Risk Analysis – CER Pages – 298 – 316 <u>Without assessing the clinical data in details, comment regarding whether or not all possible risks have been enlisted and the adequacy of risk management measures can-not be commented on.</u>
40.	Does the IFU contain the information on the use of the Device, appropriate warnings, precautions, and complications consistently with the supporting evidence provided in the CER and Risk Management Report?	☒ YES ☐ NO Comment if required:

DAVS Assessor's comments:

The subject device for which this assessment has been done have been referred to as 'The Device' in the comments and recommendations below.

- The devices have been approved by the US FDA.
- The CER is up-to-date, authored, endorsed and signed by a clinical expert. A CV for the clinical expert has been provided.
- Post market information for the predicate devices have has been provided.
- Design FMEA analyses have been provided in the risk management documentation.
- Three devices are claiming MR conditional and supporting data has been submitted.

DAVS Assessor:

Name:	s22	Date:	8/05/2017
Signature:	Signed Electronically		

Comments from Clinical assessor (Medical Officer):

It is unclear if all the Devices covered in this application have been approved by FDA and under what conditions eg MR safety indications etc. This needs to be clarified.

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Clinical evidence submitted predominantly consist of literature data which appear generalised and non-specific at this initial assessment; multiple claims of substantial equivalence of the subject Devices and multiple predicate devices and a comparator device; and post-market data that were not specific to the predicate devices alone with adverse event/complaint rate data provided without a clear analysis. A further more detailed assessment is required. It is likely that a significant amount of time would be

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[needed for in particular the assessment of the equivalence claims: the post-market data of the predicate/comparator devices; and the MRI safety for each individual Device and its labelling requirements.](#)

Does the submitted clinical evidence provide verification of the conformance with the requirements of the essential principle 14 of Schedule 1 and Part 8 of Schedule 3 of the <i>Therapeutic Goods (Medical Devices) Regulations 2002</i> ?	☐ YES / ☒ NO
--	---

Clinical assessor:

Name:	Electronically signed	Date:	11/05/2017
Signature:	Signed Electronically		

Endorsed by (if required):

Name:	s22	Date:	12/05/2017
Signature:	Signed Electronically		

Field Code Changed



Australian Government

Department of Health

Therapeutic Goods Administration

Application Audit - Level 2 Clinical Assessment – 2nd Round

TRIM Reference: [D17-701431](#)

To be completed by DAVS Assessor:

Device UPI:	<p>s22</p> <p>MOMENTUM CRT-D - G125, s22</p> <p>s22</p>
Sponsor:	Boston Scientific Pty Ltd
Manufacturer:	Cardiac Pacemakers Inc. (United States Of America)[9897]
Application ID:	<p>s22 DV-2017-DA-02403-1</p> <p>s22</p>
Submission ID:	<p>s22 DA-2017-01356-1, s22</p> <p>s22</p>
DAVS Assessor:	s22
Application TRIM	<p>E17-5437, E17-5438, E17-5442, E17-5445, E17-5443, E17-5446 E17-5451, E17-5448, E17-5450</p> <p>1st Data submission - D17-324877</p>
Sponsor's submission TRIM Ref.:	<p>TRIM: D17-701387</p> <p> Q2 Q3 Q4 Q6 Q7 </p> <p> Cover Letter s41JA Notice - DA-2017-01355-1, DA-2017-01356-1, DA-2017-01357-1, DA-2017-... </p> <p>Please refer to the cover letter for an overview of sponsor responses and location of supporting information.</p>
Date submitted to TGA:	22/08/2017
Date Referred to Clinical Section:	22/08/2017
Screening for clinical data:	<p><u>Has screening been completed?</u></p> <p>Yes ☐ No ☐</p> <p>If '<u>YES</u>':</p> <p>Click here to enter a date.</p> <p><u>Name of the assessor:</u></p>

	Did the screening identify any issues? Yes ☐ No ☐ If ' <u>YES</u> ': TRIM reference for Screening Report: R16/xxxxx <i>Note: if no issues have been identified, there is no need for a screening report</i>
Clinical Round:	2 Clinical screening report: D17-344962 1 st round of clinical assessment: D17-326283

To be completed by Clinical Assessor:

Does the submitted clinical data meet the requirements of essential principle 14 of Schedule 1 and Part 8 of Schedule 3 of the Therapeutic Goods (Medical Devices) Regulations 2002?	☒ NO
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Comments & Rationale:

This is the second round of clinical assessment for a range of nine subject cardiac pacemakers. This report will review the information submitted by the sponsor relevant to the TGA questions raised from the first round of clinical assessment of the [s22](#)

[s22](#), MOMENTUM CRT-D - G125, [s22](#), from Cardiac Pacemakers Inc., collectively referred, as the "Devices" in this report. In addition, as further clinical data has been provided, the assessor will also review the previously submitted IFUs and risk management documents again this round.

Overall, the information provided for this first round of clinical assessment for the Devices was deficient in many areas. The following deficiencies have been identified. Further information was requested, as below.

Overall, this is a complex assessment, as only one clinical report has been requested to cover all nine different subject Devices. Furthermore, the data provided has been difficult and time consuming to review, due to the large quantity of data submission; non-systemic presentations of data for each device; and the amount of information that are not directly relevant to the subject devices and for the submission.

The sponsor has not provided sufficient evidence to demonstrate substantial equivalence of each individual device with another. Only generalised comparisons between groups were made. Clinical data provided contained clinic investigation data that does not pertain to the subject devices. Literature data contains some systematic review with some brief description of literature search strategies and selection process and results with no critical appraisal of individual data that are specific to each of the individual subject Device. Post-market data again was non-specific and appears to contain data pertaining to some predicate devices only. There has been no data presented for the subject Devices. With the data presented, summary of data was given but without a comparative analysis or discussion in the CER. MRI conditional statuses have been claimed for three of the subject devices. However, there have been no specific modelling data found in the submission for each of these devices. Further information required will depend on the ability of the sponsor to demonstrate substantial equivalence of these devices with another and the MR condition

of those. IFU and risk documentations cannot be assessed further due to the inadequate clinical data provided.

In summary, there is insufficient data to demonstrate that these nine subject devices are safe and perform as intended. The following information would therefore be required in order to demonstrate compliance with Essential Principles 1, 3, 6, and 14.

<i>Is additional clinical data required?</i>	YES
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1. Provide detailed descriptions of each of the nine subject devices to allow clear identifications of each of the devices; and
2. Provide clear statement(s) of the FDA regulatory status for each of the subject device, including but not limited to intended purposes/indications and MR status; and
3. Provide the electronic signature page from the endorsing clinical expert, s22 and
4. Provide a detailed and separate comparison table for each of the subject devices with its substantially equivalent device(s) (it is recommended to limit the comparison to one to two individual device only), in terms of the intended purpose of the devices and the technological and biological characteristics of the devices. If there are differences then evidence needs to be provided with expert justifications as to how each of the difference would not clinically significantly affect the performance and safety of the subject device; and
5. Provide MR status for each of the claimed substantially equivalent device for the s22
6. Provide an up-to-date systematic literature review, which pertain directly to each of the subject devices or each of their claimed substantially equivalent devices and present the data in a systematic way to allow assessment of individual subject device data separately.
7. Provide an up-to-date post-market data which pertain specifically and separate to each of the subject devices or the claimed equivalent devices, with also comparative analysis and expert report of these data to other similar marketed devices to substantiate the safety and efficacy of each of the subject device.

Assessment of the applicant response

TGA Question 1 and Response

Q1. Provide detailed descriptions of each of the nine Devices to allow clear identifications of each of the devices.

BSC Response:

Please refer to comparison document included in response to question 4 below, which provides descriptions of the nine devices and their differences.

Assessor Comments

The information submitted in response to Question 4 found to be relevant to this part of question has been copied and shown as below.

The NG4 models themselves differ in the programmable features available. s22 These models have identical hardware (except the header difference due to lead port configuration) and firmware.

PHYSICAL CHARACTERISTICS

Table 1-1 and Table 1-2 provide the physical characteristics of each NG4 model and the NG3 predecessor. Physical characteristics include the leads supported, mass, volume, and dimensions for each NG4 model. For ICD models, the device type (VR or DR) is also provided. Like their predecessor models, all NG4 devices have a maximum energy of 41 J stored with of 35 J delivered.

Table 1-1: NG4 CRT-D Family Comparison

Device Under Review (NG4 Family)	Predicate Device (NG3 Family)	Supported Lead Standard (RV/LV) RA: IS-1	Mass (g)	Vol (cc)	Dimensions (cm) (H x W x D)	Patient Contacting Materials*	Comparison
MOMENTUM CRT-D GL25	AUTOGEN CRT-D GL75 ARTG 221616	DF-1/IS-1	72.8	32.0	8.08 x 5.37 x 0.99	Epoxy - Cured epoxy thermoset polymer from M31-CL epoxy resin/amine hardener system Isoplast 2530 thermoplastic polyurethane Titanium Grade 1 per ASTM B265 and ASTM F67 Silicone rubber: platinum cure two part system consisting of dimethyl and methylvinyl siloxane copolymers and reinforcing silica Room temperature cure silicone rubber adhesive: NuSil 1514 Silicone rubber (liquid): pigment white silicone paste Copolymer of dimethylsiloxane and trifluoropropylmethyl-siloxane	Same

* There are no new materials in NG4 devices compared to the currently market released NG3 devices. Therefore, NG4 devices are biocompatible by equivalence. Nonetheless a biocompatibility assessment was performed for NG4 per BSC internal requirements as NG4 is a new product. NG4 Biocompatibility Assessment Report (92008857)

Table 1-2: NG4 ICD Family Comparison

s22

Device Under Review	Predicate Device	Supported Lead Standard (RV) RA: IS-1	Mass (g)	Vol (cc)	Dimensions (cm) (H x W x D)	VR or DR	Patient Contacting Materials*	Comparison

** There are no new materials in NG4 devices compared to the currently market released NG3 devices. Therefore, NG4 devices are biocompatible by equivalence. Nonetheless a biocompatibility assessment was performed for NG4 per BSC internal requirements as NG4 is a new product. NG4 Biocompatibility Assessment Report (92008857)*

With the detailed information provided, the assessor is satisfied that clear descriptions of the nine devices had been given and no further information is required.

TGA Question 2 and Response

Q2. Provide clear statement(s) of the FDA regulatory status for each of the subject device, including but not limited to intended purposes/indications and MR status.

BSC Response: Please find attached statement regarding FDA Regulatory status.

Assessor comments

A separate document, named FDA Letter Signed, can be found in this round of submission. The letter confirms all nine subject Devices (as highlighted below) have PMA FDA approvals.

Models Approved:

s22

The Cardiac Resynchronization Therapy - Defibrillator (CRT-D) devices approved per PMA I are:

•

•

•

•

MOMENTUM™ CRT-D Models –

s22

G125,

s22

s22

The assessor notes that the approved indication/intended use for the CRT-Ds (not the ICDs) by FDA is slightly different to those claimed of the subject devices in the application to the TGA. This will be explored further in Question and comment 4.

CRT-D:

FDA Approved	<u>CRT-D:</u> These Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with heart failure who receive stable optimal pharmacologic therapy (OPT) for heart failure and who meet any one of the following classifications: <ul style="list-style-type: none"> Moderate to severe heart failure (NYHA Class III-IV) with EF $\leq$ 35% and QRS duration $\geq$ 120 ms Left bundle branch block (LBBB) with QRS duration $\geq$ 130 ms, EF $\leq$ 30%, and mild (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class I) ischemic heart failure
To the TGA	<i>These Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients who are at risk for sudden cardiac death caused by ventricular arrhythmias and who have heart failure (including asymptomatic [NYHA Class I] ischemic heart failure) with ventricular dyssynchrony.</i>

ICD:

FDA Approved	<u>ICD:</u> Boston Scientific implantable cardioverter defibrillators (ICDs) are intended to provide ventricular antitachycardia pacing (ATP) and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.
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To the TGA	<i>Boston Scientific implantable cardioverter defibrillators (ICDs) are intended to provide ventricular antitachycardia pacing (ATP) and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.</i>
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The letter also confirms that the FDA submission for MR Conditional s22, MOMENTUM, s22, and CRT-D devices is still currently under review also. No further information is required in response to the question.

TGA Question 3 and Response

Q3. Provide the electronic signature page from the endorsing clinical expert, s22

BSC Response: Please find attached electronic signature page.

Assessor comments

The following has been provided and is considered satisfactory. No further info is required.

Doc No. 100000007248G

Signature Page 1

APPROVALS		
Meaning / Title	Signature	Date
Revision G: Periodic update of ICD/CRT-D CDSR.		
Author: Clinical Scientist	s22	23-Sep-2016 11:31 (GMT -0500)
Approvers: Director, Quality		23-Sep-2016 11:46 (GMT -0500)
Director, Quality		23-Sep-2016 12:38 (GMT -0500)
Director, Medical Safety		26-Sep-2016 08:17 (GMT -0500)
End of Approvals		

TGA Question 4 and Response

Q4. Provide a detailed and separate comparison table for each of the Devices with its substantially equivalent device(s). It is recommended to limit the comparison to one to two individual device only), in terms of the intended purpose of the devices and the technological and biological characteristics of the devices. If there are differences then evidence needs to be provided with expert justifications as to how each of the difference would not clinically significantly affect the performance and safety of the subject device.

BSC Response:

Please refer to attached document which provides detailed comparison of the subject device to the substantial equivalent devices.

Assessor comments

The submitted document, named *Attachment 1 Comparison to Predicate Device*, contained detailed comparative information between each subject device and its predicate.

Table 1-1 and 1-2 provided physical comparisons of the subjective devices and their respective predicate devices (ARTG individually provided also). This has been presented clearly and systematically.

It also states that, in comparison to the predicate devices, as “*there are no new materials in NG4 devices...Therefore, NG4 devices are biocompatible by equivalence*”.

The application states clearly that the “*NG4 family, are the exact same physical devices as the NG3 family (already ARTG listed), i.e., NG4 share the same components as the NG3 and are manufactured per the same processes on the same manufacturing line. The only difference between NG3 and NG4 are the PG firmware.*”

Table 1-4 and Table 1-5 further provides a list of the programmable features of the CRT-D and ICD devices compared to the substantial equivalent NG3 devices. Majority of the features are identical.

The differences and clinical justification are listed below.

CRT-D

Features	Comparison	Clinical Assessment: Impact on Safety and Performance Provided
LV Multi-Site Pacing	New feature on Resonate CRT-D X4 G447 Model only	<p>This is intended to improve the cardiac resynchronization therapy response by delivering two LV pulses per pacing cycle. LV MSP will only be available for CRT-D devices when using a quadripolar LV lead, model G447 only.</p> <p>This feature is supported by demonstrated substantial equivalence (as outlined in the CDSR previously submitted) to the s22 which includes MPP feature. s22 holds TGA approval under ARTG s22</p> <p>In addition to the information previously provided in the CDSR, a detailed comparison of parameters table comparing BSC G447 device with s22 feature has been provided. The table does not address the physical comparisons of the pulse generators as the physical characteristics are not relevant. BSC comparison to s22 is only for the purpose of the MSP firmware feature.</p>
HeartLogic	New Feature	<p>This is a diagnostic tool to detect gradual worsening of heart failure (HF) over days or weeks using multiple physiological measurements. The HeartLogic Index aggregates measurements from multiple device-based sensors (e.g., Heart Sounds, Thoracic Impedance, Respiration, and Night Heart Rate) and reflects changes over time in the patient's sensor trend data from their respective baseline values.</p> <p>This feature is supported by BSC validation data (HeartLogic Algorithm Validation report - attached) as well as medical literature (refer to CDSR previously submitted).</p>
Atrial Diagnostic	New Feature	<p>No impact on Safety & Performance. This is a reporting tool only. This feature consolidates all AT/AF diagnostics data on a single</p>

Features	Comparison	Clinical Assessment: Impact on Safety and Performance Provided
Reporting		report for ease of use.

ICD

Features	Comparison	Clinical Assessment: Impact on Safety and Performance Provided
Atrial Diagnostic Reporting	New Feature	No impact on Safety & Performance. This is a reporting tool only. This feature consolidates all AT/AF diagnostics data on a single report for ease of use.
HeartLogic	New Feature	<p>This is a diagnostic tool to detect gradual worsening of heart failure (HF) over days or weeks using multiple physiological measurements. The HeartLogic Index aggregates measurements from multiple device-based sensors (e.g., Heart Sounds, Thoracic Impedance, Respiration, and Night Heart Rate) and reflects changes over time in the patient's sensor trend data from their respective baseline values.</p> <p>This feature is supported by BSC validation data (HeartLogic Algorithm Validation report - attached) as well as medical literature (refer to CDSR previously submitted).</p>

Supporting documents have been also provided. Technical data provided unfortunately is beyond the assessor's expertise to comment on, however, with the systematic presentations of information and justifications now given, no further information is required from the clinical assessor's point of view. However, in assessing the substantial equivalence claims, the applicant is required to demonstrate that the clinical indications between the predicate and the subject device are identical. The assessor commented earlier that the indications provided for CRT-Ds are slightly different (more generalised) compared with that approved by FDA. The assessor here notes again that ARTG approved indications for the predicate CRT-Ds (which align with that approved by FDA) are again different to what's being claimed by the subject CRT-Ds. If the applicant wishes to continue claiming for substantial equivalence between the predicate devices and the subject devices, the claimed indications for the CRT-Ds subject devices are required to be identical to those approved for the predicate devices. Applicant will be asked to consider changing the intended use/indications for the subject CRT-Ds to align with their predicate devices approved by TGA previously. Alternatively, the applicant will need to provide substantial amount of clinical data to support efficacy and safety of each of the individual subject Device for its own intended purposes.

In consideration of the information submitted in round one of clinical assessment and the more systematic presentation and justifications of the equivalence data for this round, the assessor is satisfied that **if the proposed intended purposes of all the subject devices are identical to that of the predicate devices**, then adequate evidence has been provided to support of the substantial equivalence claims for each of the subject Devices.

s22

Assessor comments

The assessor notes that the above three subject devices are identical to their respective substantial equivalent devices, from the MR conditional status point of view. No further question is required.

TGA Question 6 and Response

Q6. Provide an up-to-date systematic literature review, which pertain directly to each of the Devices or each of their claimed substantially equivalent devices and present the data in a systematic way to allow assessment of the individual Device data separately.

BSC Response:

Please find attached literature review which focused on the substantial equivalent devices (NG3) and the subject devices NG4.

The literature search focused on studies for the new features incorporated into the NG4 devices together with a general search on anything related to the ICD/CRT-D safety & performance of NG3 (substantial equivalent device).

Additionally a manual search was performed using the NG4 names and models and as expected there was no published literature given the device is new to market.

Assessor comments

Addendum to Clinical Data Summary Report Expanded Literature Review document has been provided for the literature update on 16 August 2017. The document provides an additional literature review to support the safety and performance of new features in the NG4 family. The new features, listed and described previously, in summary include:

- HeartLogic in which multiple sensors are integrated into a diagnostic tool to detect impending worsening of heart failure, and
- LV Multi-Site Pacing (MSP) in which a stimuli is delivered to two electrodes on a quadripolar left ventricular lead, and

- Atrial Diagnostics Reporting, in which diagnostic information on atrial arrhythmias previously available on earlier generation devices are now consolidated into a single report.

Updated literature search for the new features has been performed with key words clearly listed. General search of ICD/CRT-D devices for both the NG3/NG4 family have also been performed. Clear literature search protocols (detailed in Appendix found) including the database, search terms, period covered by search, and inclusion and exclusion criteria, have been given. These appear to be appropriate. Selection process has been described. Selected publications have been listed and summarised. Critical appraisals of individual studies have not been provided of the expected details. General summaries of the findings of the selected groups of studies have been provided. In consideration that no major safety or performance issues relevant to the new features of the subject devices have been identified currently, along with the accepted claim of substantial equivalence with the predicate devices, **(only if the proposed intended purposes of all the subject devices are identical to that of the predicate devices)**, further request of more detailed critical appraisal of individual studies and summaries are not likely to change the outcome of the assessment. No further information is therefore required at this stage.

TGA Question 7 and Response

Q7. Provide an up-to-date post-market data which pertain specifically and separate to each of the Devices or the claimed equivalent devices, with also comparative analysis and expert report of these data to other similar marketed devices to substantiate the safety and efficacy of each of the Devices.

BSC Response:

Please find attached updated post market data for the substantial equivalent device and the subject devices.

Assessor comments

A separate document named MARKET EXPERIENCE DATA has been provided for this round of assessment. Reliability data are all-time through 01 August 2017 for the currently marketed NG4 ICG and CRT-D's. The predicate AUTOGEN marketing data has also been provided. Up-to-date sales data has been copied and inserted as below.

Table 1: NG4 ICD and CRT-D Device Sales by Region/Geographys47G
**Table 2: AUTOGEN (NG3) Device Sales by Region/Geography**s47G


This sales data is further matched with the MDR/MDV data as below, with important overview data copied and inserted below.

Table 2: Worldwide Device Sales and MDR / MDV Data by Model – (NG4)s47G


Table 53: Worldwide Device Sales and MDR / MDV Data by Model – AUTOGEN (NG3)

s47G

Table 5: MDR Summary – NG4

MDR Type	No. MDR Reports	MDR % (No. MDR Reports / Units Sold)
Device Malfunction	1	0.134%
PG Header/Lead Interface Issue	1	
Grand Total of all MDR Types	1	

Table 61: MDR Summary – AUTOGEN

MDR Type	No. MDR Reports	MDR % (No. MDR Reports / Units Sold)
Patient Death Situations where device malfunction may have contributed to a patient's death.	7	0.017%
Patient Death	7	

MDR Type	No. MDR Reports	MDR % (No. MDR Reports / Units Sold)
Device Malfunction	196	0.483%
Serious Injury/Surgical Intervention Device Malfunction resulting in patient injury (including syncopal episodes) or requiring surgical intervention to prevent serious injury.	170	0.419%

Discussion of data has been provided. *The most commonly report observation resulting in an MDV/MDR involve an impedance issue, either “impedance issue,” or “pacing or shock impedance high.” High and low impedance measurements (i.e., impedance issue) can be related to lead design, lead integrity issues, lead to device connection, or lead to tissue interface. Lead impedance measurements are a diagnostic tool used to assess system integrity. High and low impedance measurements do not directly result in adverse patient effects. Rather, they are a prompt to the clinician that the lead impedance value has moved outside of the typical operating range, and further investigation may be appropriate to determine if system performance remains clinically suitable or has been compromised.*

There were 7 reported observations that met the criteria for a Patient Death MDR - observations where device may have contributed to a patient's death. Although the observation may be related to the device and/or lead, it can also be caused by a number of other factors including patient condition, environmental, or extrinsic factors.

The Physician Technical Manual for BSC lists Potential Adverse Events associated with implantation of these products (based on the literature and on pulse generator and/or lead implant experience). The observations reported to BSC involving the Autogen device are consistent with known potential adverse events...

Based on the post-market reliability data provided in this document, as well as previously conducted literature review, compiled clinical data risk analysis, BSC asserts that there is sufficient and well established clinical evidence to support the safety and performance of the devices for use in a clinical setting.

None of the 7 reported deaths pertain to the subject devices. In comparison of the NG3 and NG4 post-market data, the relatively higher MDV rate (%MDV/WW sales) for Model G124 of 2.38% could possibly an overestimate of events due to the low world-wide sales number of ^{547G} units only. Overall, the assessor is satisfied with the post market-data provided. No further information or justification(s) is required.

Instructions for Use

With the additional data in terms of up-to-date literature and post-market data, the assessor is able to further assess the provided two IFUs for the two groups of subject Devices.

The IFUs for subject ICDs and CRT-Ds cover all the subject devices appropriately. The IFUs contain detailed information on device description, indications and usage, contraindications, warnings, precautions, potential adverse events, cautions and MRI conditional warnings and precautions etc.

The device description, indications and contraindications were consistent with those outlined in the CER. The IFU includes a list of compatible devices, warnings, precautions, patient counselling information and adverse effects, which are considered appropriate.

The listed range of potential adverse events appear to align with the device-specific risks identified in the literature search and in the available post-market data of the both the predicate devices and subject devices.

No further information is required.

Risk Management

Risk analysis report has been provided along with safety risk management process tables. This can be found in Appendix F – Risk Analysis submitted for round one of clinical assessment.

-  Safety Risk Management Process.pdf
-  NG4 Safety Risk Management Report.pdf
-  HeartLogic - MSP Hazard Analysis Report.pdf
-  CRM MultiSENSE Safety Risk Management Plan.pdf

Safety Risk Management Process documents confirms that the CRM safety risk management process is in complaint with ISO 14971. Risk stratification process and definitions have been described. The HeartLogic-MSP Hazard Analysis Report covers the following devices (with all subject devices included):

Table 16 - Model Numbers

PLE Product	VR Models	DR Models	CRT-D Models
s22			
NG4 E	D120	D121	s22 G125 s22

An overview of the Hazard Analysis Report appear to suggest that the risks associated with the use of the device have been adequately identified based on the updated clinical information from eh literature and the post-market data provided, at this time. Details of risk management activities appear to demonstrate appropriate procedures to address possible risks associated with the use of the devices. Safety Risk Management Report further confirms the following;

The Development Phase activities in the Safety Risk Management Plan have been appropriately implemented and the overall residual risk of this product (or project output) is acceptable to the undersigned. Specifically, ...

- the Hazard Analysis Report includes a risk evaluation for each identified hazardous situation,
- the Hazard Analysis Report shows the traceability of each hazardous situation to risk control measures,
- the Hazard Analysis Report provides evidence of the implementation of the risk control measures by designation of specific design requirements,
- evidence of the verification of the design requirements is stored in the Design History File, and
- the Hazard Analysis Report concludes that the residual risk is acceptable when weighed against the intended benefits to the patient.

The assessor must clearly states here that the above assessor's comments are based on an overview of the Hazard Analysis Report and not on the assessment of the entire 1187 pages of report provided due to feasibility issue.

No further information is required.

Conclusions and Recommendations:

The applicant has provided further clinical evidence to demonstrate the safety or performance of the subject Devices. Majority of the clinical data pertain to the substantially equivalent devices, which have been clearly listed, compared to and discussed in details now. Further evidence has been provided in a systematic way to support the substantial equivalence claims for each of the subject devices. However, one issue remains currently and requires further information, to support the substantial equivalence claims.

For the subject CRT-D devices, if the applicant wishes to continue claiming for substantial equivalence between the predicate devices and the subject devices, the claimed intended use of the CRT-Ds subject devices are required to be identical to those approved for the predicate devices on the ARTG. The applicant needs to consider changing intended use for the subject CRT-Ds to align with their predicate devices approved by TGA previously. Currently the indications are listed as below.

ARTG approved intended use for the predicate CRT-Ds	<p>Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with heart failure who receive stable optimal pharmacologic therapy (OPT) for heart failure and who meet any one of the following classifications:</p> <ul style="list-style-type: none"> • Moderate to severe heart failure (NYHA Class III-IV) with EF $\leq$ 35% and QRS duration $\geq$ 120 ms • Left bundle branch block (LBBB) with QRS duration $\geq$ 130 ms, EF $\leq$ 30%, and mild (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class I) ischemic heart failure. <p>Boston Scientific CRT-Ds are also intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.</p>
Subject CRT-D devices intended use	<p><i>"These Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients who are at risk for sudden cardiac death caused by ventricular arrhythmias and who have heart failure (including asymptomatic [NYHA Class I] ischemic heart failure) with ventricular dyssynchrony."</i></p>

Alternatively if the applicant does not wish to change the claimed intended purposes, the applicant will be required to provide further clinical data, pertaining directly to each of the

subject CRT-D devices to support the efficacy and safety for its intended purposes (and under the specified MRI conditions for the s22

Is additional clinical data required?	YES
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1. Provide amendments to the intended use of the subject CRT-D devices (i.e. s22 MOMENTUM CRT-D - G125, s22 on the TGA eBS, the CER and the IFU to align with that of the predicate devices.

Name, date and signature of Clinical Assessor:

Name:	s22	Date:	21/09/2017
Signature:	Electronically signed		



Australian Government

Department of Health

Therapeutic Goods Administration

Application Audit - Level 2 Clinical Assessment – 3rd Round

TRIM Reference: [D17-944425](#)

To be completed by DAVS Assessor:

Device UPI:	s22 MOMENTUM CRT-D - G125, s22
Sponsor:	Boston Scientific Pty Ltd
Manufacturer:	Cardiac Pacemakers Inc. (United States Of America)[9897]
Application ID:	s22 DV-2017-DA-02403-1 s22
Submission ID:	s22 DA-2017-01356-1, s22 s22
DAVS Assessor:	s22
Application TRIM	(E17-5437, E17-5438, E17-5442, E17-5445, E17-5443, E17-5446 E17-5451, E17-5448, E17-5450 1 st Data submission - D17-324877 2 nd Data submission - D17-705246
Sponsor's submission TRIM Ref.:	<u>Sponsor's response to Rd 2 Clinical:</u> TRIM: D17-943964 <ul style="list-style-type: none"> Addendum to CER Revised IFU
Date submitted to TGA:	10/11/2017
Date Referred to Clinical Section:	15/11/2017
Clinical Round:	3 Clinical screening report: D17-344962 1 st round of clinical assessment: D17-326283 2 nd round of clinical assessment: D17-701431

To be completed by Clinical Assessor:

Does the submitted clinical data meet the requirements of essential principle 14 of Schedule 1 and Part 8 of Schedule 3 of the Therapeutic Goods (Medical Devices) Regulations 2002?	YES
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Comments & Rationale:

This is the final round of clinical assessment. Only information relevant to the clinical question raised will be assessed here.

Last round of assessment was concluded as below:

“The applicant has provided further clinical evidence to demonstrate the safety or performance of the subject Devices. Majority of the clinical data pertain to the substantially equivalent devices, which have been clearly listed, compared to and discussed in details now. Further evidence has been provided in a systematic way to support the substantial equivalence claims for each of the subject devices. However, one issue remains currently and requires further information, to support the substantial equivalence claims.

For the subject CRT-D devices, if the applicant wishes to continue claiming for substantial equivalence between the predicate devices and the subject devices, the claimed intended use of the CRT-Ds subject devices are required to be identical to those approved for the predicate devices on the ARTG. The applicant needs to consider changing intended use for the subject CRT-Ds to align with their predicate devices approved by TGA previously. Currently the indications are listed as below.

ARTG approved intended use for the predicate CRT-Ds	<p><i>Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with heart failure who receive stable optimal pharmacologic therapy (OPT) for heart failure and who meet any one of the following classifications:</i></p> <ul style="list-style-type: none"> <i>• Moderate to severe heart failure (NYHA Class III-IV) with EF $\leq$ 35% and QRS duration $\geq$ 120 ms</i> <i>• Left bundle branch block (LBBB) with QRS duration $\geq$ 130 ms, EF $\leq$ 30%, and mild (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class I) ischemic heart failure.</i> <p><i>Boston Scientific CRT-Ds are also intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.</i></p>
Subject CRT-D devices intended use	<p><i>“These Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients who are at risk for sudden cardiac death caused by ventricular arrhythmias and who have heart failure (including asymptomatic [NYHA Class I] ischemic heart failure) with ventricular dyssynchrony.”</i></p>

Alternatively if the applicant does not wish to change the claimed intended purposes, the applicant will be required to provide further clinical data, pertaining directly to each of the subject CRT-D devices to support the efficacy and safety for its intended purposes (and under the specified MRI conditions for the [s22](#) 

The following information has been requested:

- 1. Provide amendments to the intended use of the subject CRT-D devices (i.e. [s22](#) , MOMENTUM CRT-D - G125, [s22](#)  on the TGA eBS, the CER and the IFU to align with that of the predicate devices.**

Applicant Response

"In response to the section 41JA notice, Boston Scientific have decided to amend the intended purpose so it is consistent with the claimed equivalent devices".

Assessor's Comment

The applicant has submitted the amended IFU and CER to reflect change in IFU to align with that of the predicate devices.

Page 5 of the amended IFU now shows the following:

INDICATIONS AND USAGE

These Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with heart failure who receive stable optimal pharmacologic therapy (OPT) for heart failure and who meet any one of the following classifications:

- Moderate to severe heart failure (NYHA Class III-IV) with EF $\leq$ 35% and QRS duration $\geq$ 120 ms
- Left bundle branch block (LBBB) with QRS duration $\geq$ 130 ms, EF $\leq$ 30%, and mild (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class I) ischemic heart failure

Boston Scientific CRT-Ds are also intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

This is now consistent with that of the predicate devices.

No further information is required.

Is additional clinical data required?	YES ☐ / NO ☒
--	--

Name, date and signature of Clinical Assessor:

Name:	s22	Date:	15/11/2017
Signature:	Electronically signed		

From: s22
To: [REDACTED]
Subject: RE: {External} Clarification on ME /QMS certificate for reclass application - Boston Scientific Pty Ltd- Cardiac Implants [SEC=OFFICIAL]
Date: Wednesday, 2 November 2022 7:55:08 AM
Attachments: [image002.png](#)
[image003.png](#)
[CRM_MDR_730391_Exp2026May24.pdf](#)

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Good Morning s22

The medical devices you have listed below fall under the RESONATE Family of CRT-Ds and ICDs and are covered by scope of certificate MDR 735821 R000. Please find attached the same, but updated, QMS certificate. I have just submitted a variation to Manufacturer's Evidence (DV-2021-MC-14238-1) to reflect the updated QMS certificate.

Thanks

Kind regards,

s22

s22 | Regulatory Affairs Specialist, CRM & EP | Ph: s22 | Boston Scientific Australia and New Zealand

From: s22@Health.gov.au>
Sent: Tuesday, 1 November 2022 4:49 PM
To: s22@bsci.com>
Subject: {External} Clarification on ME /QMS certificate for reclass application - Boston Scientific Pty Ltd- Cardiac Implants [SEC=OFFICIAL]

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe. Be Security Conscious!

Hi s22,

Good afternoon. I am currently working on reclassification of theses medical devices as detailed below.

Submission Number	UPI	ME	MDR Certificate number
s22			
DA-2022-09269-1	MOMENTUM CRT-D Model G125	DV-2021-MC-14238-1	730391R000
s22			

s22

On review of the QMS certificate it is noted that the subject devices are not included in the scope of the certificate (attached). Only models that is covered by this certificates are EMBLEM. Please see below.



Can you please confirm that incorrect ME has been uploaded for these devices? Once I received your confirmation I will pushback these applications for correct ME.

Kind Regards

s22

Departmental Officer – Devices Applications Section

Medical Devices Authorisation Branch – Medical Devices and Product Quality Division
Australian Government, Department of Health and Aged Care

T: s22 @health.gov.au

Location: 27 Scherger Dr, Fairbairn

Australian Capital Territory 2609

PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission.

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."



By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 730391 R000

Manufacturer: Cardiac Pacemakers, Inc., a Subsidiary of Boston Scientific Corporation**Address:**

4100 Hamline Avenue North
St. Paul
Minnesota
55112-5798
USA

Single Registration Number: US-MF-000010993**EU Authorised Representative:** Guidant Europe NV/SA, Boston Scientific**Address:**

Green Square, Lambroekstraat 5D
Diegem
1831
Belgium

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

s22

s22

Senior Vice President Medical Devices

First Issued: **2021-05-25**Date: **2022-08-24**Expiry Date: **2026-05-24**

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Page 1 of 3

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.



By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 730391 R000

Device Schedule: Class III

Class III, Implantable	Intended purpose
EMBLEM S-ICD System	See MDR 730712
EMBLEM MRI S-ICD System	
EMBLEM S-ICD Electrodes and System Accessories	See MDR 743490
RESONATE Family of CRT-Ds and ICDs	See MDR 735821
AUTOGEN Family of CRT-Ds and ICDs	
Ingevity MRI Leads Family	See MDR 733839
Ingevity+ Leads Family	
FINELINE™ II Sterox Pace/Sense Lead	See MDR 737944
FINELINE™ II Sterox EZ Pace/Sense Lead	
Suture Sleeve	
RELIANCE 4- FRONT™ Pace/Sense and Defibrillation Leads	See MDR 737814
Suture Sleeves, Attachable	
LUX-Dx Insertable Cardiac Monitor System	See MDR 749618
Class III	Intended purpose
LATITUDE Programming System (and associated software)	See MDR 737950
LATITUDE NXT Patient Management System	See MDR 742788

First Issued: **2021-05-25**Date: **2022-08-24**Expiry Date: **2026-05-24**

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Page 2 of 3

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.



By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 730391 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference number	Action
2021-05-25	3223055	Issued.
2021-07-21	3283734	Supplemented – Addition of MDR 735821. Amended – s47 s47
2021-12-13	3269288	Supplemented – Addition of MDR 733839. Amended – s47 s47
2022-03-07	3310413	Supplemented – Addition of MDR 737950. Amended – s47 s47 s47
2022-04-07	3310376	Supplemented – Addition of MDR 737944.
2022-04-13	3309683	Supplemented – Addition of MDR 737814.
2022-04-26	3369327	Supplemented – Addition of MDR 742788. Amended – s47 s47
Current	3429565	Supplemented – Addition of MDR 749618

First Issued: **2021-05-25**Date: **2022-08-24**Expiry Date: **2026-05-24**

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Page 3 of 3

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.



By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 730391 R000

Date: 2022-08-24

Critical Subcontractor /Crucial Supplier	Service(s) supplied
s47	

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By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 730391 R000

Date: **2022-08-24**

Critical Subcontractor/Crucial Supplier	Service(s) supplied
[Redacted Content]	

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By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 730391 R000

Date: **2022-08-24**

Critical Subcontractor/Crucial Supplier	Service(s) supplied
<div>s47</div>	

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 730391 R000

Date: 2022-08-24

Critical Subcontractor/Crucial Supplier	Service(s) supplied
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s47

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Australian Government
Department of Health
 Therapeutic Goods Administration

Medical Devices Program

Internal Form

DAS FORM 4.a	Medical Device Application Without an Audit Assessment Checklist		
Comes under	DAS SOP 4 Assessing an application without an audit		
Applicable to	Devices Applications Section	Authorised by	s22 Director, DAS
Date issued	21 Jul 2021	Version #	1.0

Application Details

Submission ID

DA-2022-09269-1

Application ID

DV-2022-DA-23478-1

TRIM Reference

[E22-626085](#)

Sponsor Name

Boston Scientific Pty Ltd

Manufacturer Name:

Cardiac Pacemakers Inc

UPI/Sponsor's reference

MOMENTUM CRT-D Model G125

Classification

III

GMDN Term & Code

Biventricular pacemaker/defibrillator [47270]

Outcome of the assessment/recommendation:

- ☐ Seek advice from the delegate
 ☐ Application has failed preliminary assessment
- ☐ Sponsor requested to withdraw application
 ☒ Decision to include kind of device in ARTG according to S41FF
- ☐ Impose conditions under S41FO
 ☐ Select application for audit under S41FH
- ☒ I confirm that I have the appropriate delegation under the *Therapeutic Goods Act 1989*

Name	s22		
Signature	Signed Electronically	Date	2-11-2022

Description of the device

Please include images and references to the relevant documents if required

<p>The application is for the reclassification of the ARTG entry 296564 from AIMD to Class III to comply with the new regulations. ¹</p>	
<p>AS per Application</p>	
Intended purpose:	<p>Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with heart failure who receive stable optimal pharmacologic therapy (OPT) for heart failure and who meet any one of the following classifications:</p> <ul style="list-style-type: none"> • Moderate to severe heart failure (NYHA Class III-IV) with EF $\leq$ 35% and QRS duration $\geq$ 120 ms • Left bundle branch block (LBBB) with QRS duration $\geq$ 130 ms, EF $\leq$ 30%, and mild (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class I) ischemic heart failure. <p>Boston Scientific CRT-Ds are also intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.</p>
Functional description:	<p>MOMENTUM CRT-D provides ventricular tachyarrhythmia therapy, cardiac resynchronization therapy and bradycardia pacing through a range of low- and high-energy shocks using a biphasic waveform; and a choice of multiple shock vectors.</p>
<p>AS per existing ARTG 296564:</p>	
<p>Intended Purpose</p> <p>Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with heart failure who receive stable optimal pharmacologic therapy (OPT) for heart failure and who meet any one of the following classifications:</p> <ul style="list-style-type: none"> • Moderate to severe heart failure (NYHA Class III-IV) with EF $\leq$ 35% and QRS duration $\geq$ 120 ms • Left bundle branch block (LBBB) with QRS duration $\geq$ 130 ms, EF $\leq$ 30%, and mild (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class I) ischemic heart failure. <p>Boston Scientific CRT-Ds are also intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.</p>	
<p>Functional Description</p> <p>MOMENTUM CRT-D provides ventricular tachyarrhythmia therapy, cardiac resynchronization therapy and bradycardia pacing through a range of low- and high-energy shocks using a biphasic waveform; and a choice of multiple shock vectors.</p>	

¹ <https://www.tga.gov.au/resource/reclassification-active-implantable-medical-devices-aimd>

Part 1 – Application

Information provided in the application – Manufacturer's Evidence	
Manufacturer's Evidence ID Application- D22-6040385	DV-2021-MC-14238-1
<i>Conformity assessment document issued by (TGA Conformity Assessment Certificate/Notified body/MDSAP/US FDA/Health Canada/Japan)</i>	Notified Body
Regulator/Certification Body name and ID	NB -2797 BSI Group, Netherlands QMS

Any relevant information (e.g. is certificate current and if it expired, has it been replaced and when; does the scope of the certificate cover the kind of device/was ME stated correctly, and if it was not, has this information been corrected and when; etc.):

MDR QMS - [D22-6038925](#)

EU MDR 2017/745, Annex IX, Chapter I and III



EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 730391 R000

Manufacturer: Cardiac Pacemakers, Inc., a Subsidiary of Boston Scientific Corporation

Address:
4100 Hamline Avenue North
St. Paul
Minnesota
55112-5798
USA

Single Registration Number: US-MF-000010993

EU Authorised Representative: Guidant Europe NV/SA, Boston Scientific

Address:
Green Square, Lambroekstraat 5D
Diegem
1831
Belgium

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb Implantable devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

s22

s22

Senior Vice President Medical Devices

First issued: 2021-05-25

Date: 2022-08-24

Expiry Date: 2026-05-24



EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 730391 R000

Device Schedule: Class III

Class III, Implantable	Intended purpose
EMBLEM S-ICD System	See MDR 730712
EMBLEM HRI S-ICD System	
EMBLEM S-ICD Electrodes and System Accessories	See MDR 743490
RESONATE Family of CRT-Ds and ICDs	See MDR 735821
AUTOGEN Family of CRT-Ds and ICDs	
Ingevity HRI Leads Family	See MDR 733839
Ingevity+ Leads Family	
FINELINE™ II Sterox Pace/Sense Lead	See MDR 737944
FINELINE™ II Sterox EZ Pace/Sense Lead	
Suture Sleeve	
RELIANCE 4- FRONT™ Pace/Sense and Defibrillation Leads	See MDR 737814
Suture Sleeves, Attachable	
LUX-Dx Insertable Cardiac Monitor System	See MDR 749618
Class III	Intended purpose
LATITUDE Programming System (and associated software)	See MDR 737950
LATITUDE NXT Patient Management System	See MDR 742788

The sponsor has confirmed that Momentum CRT -D Devices falls under Resonate Family of CRT-Ds-[D22-6038909](#)

'The medical devices you have listed below fall under the RESONATE Family of CRT-Ds and ICDs and are covered by scope of certificate MDR 735821 R000. Please find attached the same, but updated, QMS certificate. I have just submitted a variation to

Information provided in the application – Manufacturer's Evidence	
	<p>Manufacturer's Evidence (DV-2021-MC-14238-1) to reflect the updated QMS certificate.'-</p> <p>TDAC 735821 R000 verifies the claim. -D22-6033620</p>
<p>Does the Notified Body have accreditation to assess the kind of device (under Medical Devices Directive 93/42/EEC and/or Active implantable medical devices 90/385/EEC or MDR 2017/745?</p>	<p>☒ Yes ☐ No</p>

Information provided in the application – Manufacturer's Evidence

Any other information if relevant:

EU TDAC - [D22-6033620](#)

EU MDR 2017/745, Annex IX, Chapter II

bsi.



EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 735821 R000

Manufacturer: Cardiac Pacemakers, Inc., a Subsidiary of Boston Scientific Corporation

Address:
4100 Hamline Avenue North
St. Paul
Minnesota
55112-5798
USA

Single Registration Number: Not Available

EU Authorised Representative: Guidant Europe NV/SA, Boston Scientific

Address:
Green Square, Lambrackstraat 50
Diegem
1831
Belgium

Scope: See attached Device Schedule

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2757):

s22

s22

Senior Vice President Medical Devices

First issued: 2021-07-21

Date: 2021-07-21

Expiry date: 2026-07-20

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Page 1 of 10

bsi.



EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 735821 R000

RESONATE Family of CRT-Ds			
Device Name	Model Number	Connector Type	MR Conditional
MOMENTUM CRT-D	G104	RA: TS-1, RV: DS-1, LV: TS-1	Yes
	G125	RA: TS-1, RV: TS-1/DS-1, LV: TS-1	Yes
	G135	RA: TS-1, RV: TS-1/DS-1, LV: DS-1	No
MOMENTUM X4 CRT-D	G120	RA: DS-1, RV: DS-1/DS-1, LV: DS-1	Yes
	G136	RA: DS-1, RV: DS-1/DS-1, LV: DS-1	Yes
CHAMBER CRT-D	G324	RA: TS-1, RV: DS-1, LV: TS-1	Yes
	G325	RA: TS-1, RV: TS-1/DS-1, LV: TS-1	Yes
CHARISMA X4 CRT-D	G320	RA: TS-1, RV: TS-1/DS-1, LV: TS-1	Yes
	G337	RA: DS-1, RV: DS-1, LV: DS-1	Yes
	G347	RA: DS-1, RV: DS-1, LV: DS-1	Yes
VIGILANT CRT-D	G348	RA: TS-1, RV: DS-1/DS-1, LV: DS-1	Yes
	G374	RA: TS-1, RV: DS-1, LV: TS-1	Yes
	G375	RA: TS-1, RV: TS-1/DS-1, LV: TS-1	Yes
VIGILANT X4 CRT-D	G320	RA: DS-1, RV: DS-1/DS-1, LV: DS-1	Yes
	G337	RA: DS-1, RV: DS-1, LV: DS-1	Yes
	G347	RA: DS-1, RV: DS-1, LV: DS-1	Yes
	G348	RA: TS-1, RV: DS-1/DS-1, LV: DS-1	Yes

Additional Information: All CRT-Ds contain the extended longevity (EL) battery.

Preliminary assessment		N/A means 'Not application and/or "not enough information to be assessed"
<p>Paragraph 41FD(c) – Is the kind of device correctly classified according to the medical device classifications?</p> <p>(Medical devices are classified based on its intended purpose, refer Division 3.1 and Schedule 2 or Schedule 2A for IVD of MD Regulations)</p> <p>Provide relevant information, including Class of the device, classification rule(s) that apply and justification if required below:</p>	☒ Yes ☐ No ☐ N/A	
<p>Class III as per classification rule 5.7 (1), Schedule 2 of the MD Regulations.</p>		
<p>Is this medical device one of the kind specified under MD Regulation 4.1 made for the purposes of section 41EA that requires the manufacturer to have a TGA conformity assessment certificate before an application for inclusion of that device in ARTG can be made, and no such certificate is in force?</p> <p>If it is not, provide relevant information below:</p>	☐ Yes ☐ No ☒ N/A	
<p>Is application accompanied by the kind of information and in a form determined for the classification of medical device? (Refer Table 2 of the guidance 'Use of market authorisation evidence from comparable overseas regulators / assessment bodies for medical devices')</p> <p>If it is not, provide relevant information below:</p>		
<p>Paragraph 41FD(f) – Have the appropriate conformity assessment procedure or requirements, comparable to the conformity assessment procedure been applied to the kind of device?</p> <p>If not, provide relevant information below:</p>		
<p>Paragraph 41FD(e) – Does the applicant have available sufficient information to substantiate the application of the conformity assessment procedures/ comparable procedures, or have procedures in place, including a written agreement with the manufacturer of the kind of device, to ensure that information can be obtained from the manufacturer within the period specified in the regulations?</p> <p>If it is not, provide relevant information below:</p>		

Preliminary assessment		N/A means 'Not application and/or "not enough information to be assessed"
Is the device in the application a medical device used for a special purpose (according to Regulation 3.10), e.g. procedure pack? If so, provide relevant information below:	☐ Yes ☒ No ☐ N/A	

Part 2 – Application Assessment

Application assessment		N/A means 'Not application and/or 'not enough information to be assessed'																																																											
Was the application made for a kind of device?	☒ Yes ☐ No ☐ N/A																																																												
Is the device nomenclature system codes (GMDN) the relevant preferred term/collective term for the devices of the kind (Regulation 1.7)?	☒ Yes ☐ No ☐ N/A																																																												
Provide any relevant information below:																																																													
<p>Cardiac resynchronization therapy implantable defibrillator 47270</p> <p>An implantable, battery-powered device consisting of a hermetically-sealed pacing pulse generator and an integrated defibrillation pulse generator with leads in the right ventricle, in a coronary vein over the left ventricle, and often in the right atrium (triple chamber). In addition to conventional pacing and defibrillation functions, the device is intended to provide cardiac resynchronization therapy (CRT) through biventricular electrical stimulation to synchronize right and left ventricular contractions for more effective blood pumping to treat symptoms of heart failure (e.g., shortness of breath, easy fatigue) and serious heart-rhythm problems [CRT defibrillator (CRT-D)].</p>																																																													
For Class III and AIMD, does the unique product identifier (UPI) stated in the application accurately identify the devices of the kind?	☒ Yes ☐ No ☐ N/A																																																												
If the UPI does not appear to be correct, provide relevant information (including if it has been amended/corrected in the application, or if other application is required, etc.) below:																																																													
AS per TDAC - D22-6033620																																																													
<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: center;">  <p>EU Technical Documentation Assessment Certificate Regulation (EU) 2017/745, Annex IX Chapter II</p> <p>MDR 735821 R000</p> </div> <div style="text-align: center;">  <p>By Royal Charter</p> </div> <div style="text-align: center;">  </div> </div> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="4">RESONATE Family of CRT-Ds</th> </tr> <tr> <th>Device Name</th> <th>Model Number</th> <th>Connector Type</th> <th>MR Conditional</th> </tr> </thead> <tbody> <tr> <td rowspan="3">MOMENTUM CRT-D</td> <td>G124</td> <td>RA: IS-1, RV: DF4, LV: IS-1</td> <td>Yes</td> </tr> <tr> <td>G125</td> <td>RA: IS-1, RV: IS-1/DF-1, LV: IS-1</td> <td>Yes</td> </tr> <tr> <td>G126</td> <td>RA: IS-1, RV: IS-1/DF-1, LV: LV-1</td> <td>No</td> </tr> <tr> <td rowspan="2">MOMENTUM X4 CRT-D</td> <td>G128</td> <td>RA: IS-1, RV: IS-1/DF-1, LV: IS4</td> <td>Yes</td> </tr> <tr> <td>G138</td> <td>RA: IS-1, RV: IS-1/DF-1, LV: IS4</td> <td>Yes</td> </tr> <tr> <td rowspan="3">CHARISMA CRT-D</td> <td>G324</td> <td>RA: IS-1, RV: DF4, LV: IS-1</td> <td>Yes</td> </tr> <tr> <td>G325</td> <td>RA: IS-1, RV: IS-1/DF-1, LV: IS-1</td> <td>Yes</td> </tr> <tr> <td>G328</td> <td>RA: IS-1, RV: IS-1/DF-1, LV: IS4</td> <td>Yes</td> </tr> <tr> <td rowspan="4">CHARISMA X4 CRT-D</td> <td>G337</td> <td>RA: IS-1, RV: DF4, LV: IS4</td> <td>Yes</td> </tr> <tr> <td>G347</td> <td>RA: IS-1, RV: DF4, LV: IS4</td> <td>Yes</td> </tr> <tr> <td>G348</td> <td>RA: IS-1, RV: IS-1/DF-1, LV: IS4</td> <td>Yes</td> </tr> <tr> <td>G224</td> <td>RA: IS-1, RV: DF4, LV: IS-1</td> <td>Yes</td> </tr> <tr> <td rowspan="2">VIGILANT CRT-D</td> <td>G225</td> <td>RA: IS-1, RV: IS-1/DF-1, LV: IS-1</td> <td>Yes</td> </tr> <tr> <td>G228</td> <td>RA: IS-1, RV: IS-1/DF-1, LV: IS4</td> <td>Yes</td> </tr> <tr> <td>VIGILANT X4</td> <td>G237</td> <td>RA: IS-1, RV: DF4, LV: IS4</td> <td>Yes</td> </tr> </tbody> </table>			RESONATE Family of CRT-Ds				Device Name	Model Number	Connector Type	MR Conditional	MOMENTUM CRT-D	G124	RA: IS-1, RV: DF4, LV: IS-1	Yes	G125	RA: IS-1, RV: IS-1/DF-1, LV: IS-1	Yes	G126	RA: IS-1, RV: IS-1/DF-1, LV: LV-1	No	MOMENTUM X4 CRT-D	G128	RA: IS-1, RV: IS-1/DF-1, LV: IS4	Yes	G138	RA: IS-1, RV: IS-1/DF-1, LV: IS4	Yes	CHARISMA CRT-D	G324	RA: IS-1, RV: DF4, LV: IS-1	Yes	G325	RA: IS-1, RV: IS-1/DF-1, LV: IS-1	Yes	G328	RA: IS-1, RV: IS-1/DF-1, LV: IS4	Yes	CHARISMA X4 CRT-D	G337	RA: IS-1, RV: DF4, LV: IS4	Yes	G347	RA: IS-1, RV: DF4, LV: IS4	Yes	G348	RA: IS-1, RV: IS-1/DF-1, LV: IS4	Yes	G224	RA: IS-1, RV: DF4, LV: IS-1	Yes	VIGILANT CRT-D	G225	RA: IS-1, RV: IS-1/DF-1, LV: IS-1	Yes	G228	RA: IS-1, RV: IS-1/DF-1, LV: IS4	Yes	VIGILANT X4	G237	RA: IS-1, RV: DF4, LV: IS4	Yes
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Application assessment		
N/A means 'Not application and/or "not enough information to be assessed"		
<p>For Class III and AIMD, are the variants stated in the application correct according to the information provided?</p> <p>If the variants do not appear to be correct, provide relevant information below:</p>	☒ Yes ☐ No ☐ N/A	
<p>Does the intended purpose stated in the application appear to be correct?</p> <p>Does it indicate any concerns?</p> <p>Is it consistent with the GMDN code selected in the application?</p> <p>If no, specify and provide relevant information below:</p>		☒ Yes ☐ No ☐ N/A ☐ Yes ☒ No ☐ N/A ☒ Yes ☐ No ☐ N/A
<p>Are there any other information/device product characteristics that need to be considered in the application (e.g. the device is a procedure pack/sterile/active, etc.)?</p> <p>Are the device characteristics consistent with the intended purpose of the kind of device, GMDN code selected in then application, etc.?</p> <p>If no, specify and provide relevant information below:</p>		☒ Yes ☐ No ☐ N/A ☒ Yes ☐ No ☐ N/A
Reclassification from AIMD to Class III		
<p>Are there any known concerns about the device (specifically or in general) such as the device is a vaginal mesh or EC Certificate was issued by a notified body of concern, e.g. withdrawal from the MDD accreditation).</p> <p>Refer "Hot Topics" R16/869138</p> <p>Provide relevant information below:</p>	☐ Yes ☒ No ☐ N/A	

Information attached with the application	
N/A means 'Not application and/or "not enough information to be assessed"	
Was any other information provided with the application? If yes, specify and provide relevant information below:	☐ Yes ☒ No ☐ N/A
Declaration of Conformity [Provide the TRIM link] Is the Declaration of Conformity made in accordance to the appropriate Part of Schedule 3 of the MD Regulations and the scope covers the Device? Provide relevant information below:	☐ Yes ☐ No ☒ N/A ☐ Yes ☐ No ☒ N/A
Labelling for the medical device [Provide the TRIM link] Does the labelling comply with EP 13.2 (location) and 13.3? Provide relevant information below:	☐ Yes ☐ No ☒ N/A ☐ Yes ☐ No ☒ N/A
Instructions for use (IFU) [Provide the TRIM link] Does the labelling comply with EP 13.2 (location) and 13.3? Provide relevant information below:	☐ Yes ☐ No ☒ N/A ☐ Yes ☐ No ☒ N/A
Any other information (e.g. data from the National Joint Replacement Registry). Provide relevant information below:	☐ Yes ☐ No ☒ N/A
Paragraphs 41FD(j) – Is the information included in and with the application complete and correct?	☒ Yes ☐ No ☐ N/A

Additional comments (if required)

Provide relevant information, if not already covered above, or if further clarification is required. For example, if it is recommended to impose a condition, state the proposed draft of the conditions and the reasons why.

--

Assessor's Name	s22	Position Level	APS 6
Signature	Signed Electronically	Date	2-11-2022

Reviewers Recommendation

To be completed by an EL1 when the decision delegate is an EL2

Recommendation	
Pass Preliminary Assessment Note: If the application has not passed preliminary assessment, the Secretary is required to give notice of the refusal under section 41FG	☐ Yes ☐ No
Include Kind of Device in ARTG	☐ Yes ☐ No
Impose Conditions under section 41FO of the Act	☐ Yes ☐ No
Other: Procedure following audits – state in the notice reasons for the recommendation	☐ Yes ☐ No

Additional comments (if required)

Provide relevant information, if not already covered above, or if further clarification is required. For example, if it is recommended to impose a condition, state the proposed draft of the conditions and the reasons why.

--

Reviewer's Name

--

Position Level

--

Signature

--

Date

--

Delegate's Checklist and Decision

Delegate's Checklist	
Do you have delegation for the purposes of section 41FDB of the Act (<i>Preliminary assessment</i> of applications)?	☒ Yes ☐ No
Do you have delegation for the purposes of section 41FF if application is finalised without the audit?	☒ Yes ☐ No
Have you checked that all requirements set out under section 41FF have been considered and met in making this decision?	☒ Yes ☐ No
Specify other if required: section 41FO	☐ Yes ☒ No
Other: section 41FL	☒ Yes ☐ No

Delegate's Decision	
Pass Preliminary Assessment Note: If the application has not passed preliminary assessment, the Secretary is required to give notice of the refusal under section 41FG	☒ Yes ☐ No
Include Kind of Device in ARTG	☒ Yes ☐ No
Impose Conditions under section 41FO of the Act	☐ Yes ☒ No
Other: section 41FL	☒ Yes ☐ No

Additional comments (if required)

Provide relevant information, if not already covered above, or if further clarification is required. For example, if it is recommended to impose a condition, state the proposed draft of the conditions and the reasons why.

--

Delegate's Name	s22	Position Level	APS6
Signature	Signed Electronically	Date	8-11-2022

Version history

Version	TRIM Reference	Description of change	Author/s	Effective date
V1.0	D19-5922185	New document. Supersedes R16/879015 Updated to new template: MDB TEMP 2.1.c- Template for a FORM - Version 3.3 Reviewed/updated content to reflect current processes.	s22	22 Jul 2021



Medical Device Application

AIMD Status: Under Review

Application Change history

Application Progress Date

Date received: 28/10/2022

Review Information

Review flag: Class or Type requires review
Reclassified

Auto review required: No

ARTG & Product ID

ARTG ID:

Product ID:

Application Details

Application identifier: DV-2022-DA-23478-1

Submission identifier: DA-2022-09269-1

Sponsor's own reference: MOMENTUM CRT-D Model G125

Application for: Medical Device - Included

Are you applying for a medical device production system? No

Will you be applying for listing of this product or procedure in the Medicare Benefit Schedule (MBS)? ☒ Yes ☐ No

Will you be applying for listing of this product on the Prosthesis List? ☒ Yes ☐ No

Will you be applying for listing of this product on the Co-dependent or hybrid technology application list? ☐ Yes ☒ No

Cancel ARTG - product:

Sponsor Details

Sponsor name: Boston Scientific Pty Ltd

Contact details: s22

Contact email: s22 @bsci.com

Class Details

Class: AIMD

Is this device to be reclassified: Yes

Reclassification: Class III

Clone Source ARTG Id: 296564

Device Product Characteristics

Is the device, or any form of the device, supplied sterile: Yes

Sterilisation Method:

Is the device intended to be invasive: Yes

Is the device, or any form of the device, intended for single use: Yes

Is the device an active device: Yes

Does the device contain material or ingredients of microbial origin: No

Does the device contain material or ingredients of recombinant origin: No

Does the device contain material or ingredients manufactured or formulated using a genetically modified organism: No

Does the device contain material or ingredients of Human Origin: No

Does the device contain Human Blood or its components:

Does the device consist of: Single product only

Does the device contain material or ingredients of Animal Origin rendered non-viable: No

Animal Species:

Country of Origin:

Does any component in the procedure, kit or system contain material or ingredients of Animal Origin rendered non-viable: No

Is the device medicated: No

Is the device formulated:

Does the product contain a medicine that is supplied separately in the Australian Market: No

Does the product contain a medical device which incorporates a medicine as an integral part and that has an action ancillary to the device: No

Does the device contain a metal on metal bearing:

I declare that this device contains only components that are medical devices which have been individually certified. No

Is this a Class IIb spinal fusion device:

Is the device software: No

Manufacturer Details	
Manufacturer evidence number:	DV-2021-MC-14238-1 :Annex IX Ch. I & III - Cardiac Pacemakers St Paul (BSI MDR 730391) Exp 24May2026
Manufacturer name:	Cardiac Pacemakers Inc (A wholly owned subs of Guidant Corp A wholly owned subs of Boston Scientific Corp) (United States Of America)[9897]
Manufacturer address as on evidence:	4100 Hamline Avenue North St Paul Minnesota 55112-5798 United States Of America S [12518]

GMDNS Code and Description	
GMDNS code and description:	Biventricular pacemaker/defibrillator[47270]

Device Category Terms	
Device category 1:	
Device category 2:	
Device category 3:	

Product Details	
Unique Product Identifier (UPI):	MOMENTUM CRT-D Model G125
Total number of devices covered:	1
Functional description:	MOMENTUM CRT-D provides ventricular tachyarrhythmia therapy, cardiac resynchronization therapy and bradycardia pacing through a range of low- and high-energy shocks using a biphasic waveform; and a choice of multiple shock vectors.

Variant List		
#	Variant type	Variant range
1.	Nil variant (as 1 device)	N/A

Standard Conditions
<ul style="list-style-type: none"> - The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information. - Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Non Standard Conditions
Note: A non standard conditions must not contain semi colons.

To remove, enter item #

Declaration

41FD Matters to be certified:

The applicant must certify that:

- (a) devices of the kind in question are medical devices; and
- (b) devices of that kind are intended for a specified purpose, as ascertained under subsection 41BD(2); and
- (c) the kind of device is correctly classified according to the medical device classifications; and
- (d) devices of that kind comply with the essential principles; and
- (e) the applicant:
 - (i) has available sufficient information to substantiate that compliance with the essential principles; or
 - (ii) has procedures in place, including a written agreement with the manufacturer of the kind of devices setting out the matters required by the regulations, to ensure that such information can be obtained from the manufacturer within the period specified in the regulations; and
- (f) either:
 - (i) an appropriate conformity assessment procedure has been applied to devices of that kind; or
 - (ii) requirements, comparable to the conformity assessment procedures, have been applied to devices of that kind; and
- (g) the applicant:
 - (i) has available sufficient information to substantiate the application of the procedures referred to in subparagraph (f)(i) or the requirements referred to in subparagraph (f) (ii); or
 - (ii) has procedures in place, including a written agreement with the manufacturer of the kind of devices setting out the matters required by the regulations, to ensure that such information can be obtained from the manufacturer within the period specified in the regulations; and
- (h) both of the following are complied with in relation to devices of that kind:
 - (i) the applicable provisions of the Therapeutic Goods Advertising Code;
 - (ii) the other requirements (if any) relating to advertising applicable under Part 5-1 or under the regulations; and
- (i) devices of that kind do not contain substances that are prohibited imports for the purposes of the Customs Act 1901; and
- (ia) devices of that kind are not to be used exclusively for one or more of the purposes specified under section 41BEA; and
- (j) the information included in or with the application is complete and correct.

Note: See section 41BH for when a medical device complies with the essential principles, section 41BI for when conformity assessment procedures are taken not to have been applied to a medical device and section 41BIA for when requirements comparable to those procedures are taken not to have been applied to a medical device.

41FDA Basis of certification of conformity assessment procedures

When certifying the matter referred to in paragraph 41FD(f), the applicant must also state that the certification of the matter is based:

- (a) on a conformity assessment certificate that is in force; or
- (b) on an Australian conformity assessment body certificate that is in force; or
- (c) on an overseas regulator conformity assessment document that is in force.

This is in accordance with Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion in the Register) Determination.

IMPORTANT - It is taken that the person, who is stated in this application as the contact person, has authorised and electronically signed the declaration under section 41FD of the Act, as provided above, on behalf of the sponsor.

In electronically submitting this application to TGA, I hereby declare that in relation to this medical device the information given in this application and the above statements on this declaration form are current and correct.

PLEASE NOTE:

A false declaration will result in the device entry being removed/cancelled from the ARTG.

Signatory name of the person submitting the application.:

.....

History

Payment notification mail has been sent to MSAC & PDC on 30/10/2022

Record	Date
Fee	0
Date Paid	28/10/2022
Date Decision	

Start Dates	Finish Dates	Working Days
Application Received	28/10/2022	0
Payment Received	28/10/2022	0
Total Working Days		0



By Royal Charter

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 735821 R000

Manufacturer: Cardiac Pacemakers, Inc., a Subsidiary of Boston Scientific Corporation

Address:

4100 Hamline Avenue North
St. Paul
Minnesota
55112-5798
USA

Single Registration Number: Not Available

EU Authorised Representative: Guidant Europe NV/SA, Boston Scientific

Address:

Green Square, Lambroekstraat 5D
Diegem
1831
Belgium

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

s22

s22

Senior Vice President Medical Devices

First Issued: **2021-07-21**

Date: **2021-07-21**

Expiry Date: **2026-07-20**

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Page 1 of 10

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 735821 R000

Intended Purpose as per the Instructions for Use: Boston Scientific implantable cardioverter defibrillators (ICDs) are intended to provide ventricular antitachycardia pacing (ATP) and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

Risk Classification: Class III Implantable

Type (Codes as per (EU) 2017/2185): MDA 0101

Basic UDI-DI: 0191506000000000000084MY

RESONATE Family of ICD's				
Device Name	Model Number	Connector Type	VR or DR	MR Conditional
RESONATE HF ICD	D520	RV: IS-1/DF-1	VR	Yes
	D521	RA: IS-1, RV: IS-1/DF-1	DR	Yes
	D532	RV: DF4	VR	Yes
	D533	RA: IS-1, RV: DF4	DR	Yes
RESONATE EL ICD	D420	RV: IS-1/DF-1	VR	Yes
	D421	RA: IS-1, RV: IS-1/DF-1	DR	Yes
	D432	RV: DF4	VR	Yes
	D433	RA: IS-1, RV: DF4	DR	Yes
MOMENTUM EL ICD	D120	RV: IS-1/DF-1	VR	Yes
	D121	RA: IS-1, RV: IS-1/DF-1	DR	Yes
CHARISMA EL ICD	D320	RV: IS-1/DF-1	VR	Yes
	D321	RA: IS-1, RV: IS-1/DF-1	DR	Yes
	D332	RV: DF4	VR	Yes
	D333	RA: IS-1, RV: DF4	DR	Yes

First Issued: **2021-07-21**

Date: **2021-07-21**

Expiry Date: **2026-07-20**

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Page 2 of 10

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 735821 R000

RESONATE Family of ICD's				
Device Name	Model Number	Connector Type	VR or DR	MR Conditional
VIGILANT EL ICD	D220	RV: IS-1/DF-1	VR	Yes
	D221	RA: IS-1, RV: IS-1/DF-1	DR	Yes
	D232	RV: DF4	VR	Yes
	D233	RA: IS-1, RV: DF4	DR	Yes
PERCIVA HF ICD	D500	RV: IS-1/DF-1	VR	Yes
	D501	RA: IS-1, RV: IS-1/DF-1	DR	Yes
	D512	RV: DF4	VR	Yes
	D513	RA: IS-1, RV: DF4	DR	Yes
PERCIVA ICD	D400	RV: IS-1/DF-1	VR	Yes
	D401	RA: IS-1, RV: IS-1/DF-1	DR	Yes
	D412	RV: DF4	VR	Yes
	D413	RA: IS-1, RV: DF4	DR	Yes

Additional Information: The PERCIVA models contain the standard longevity (SL) battery. All other ICDs contain the extended longevity (EL) battery.

First Issued: **2021-07-21**

Date: **2021-07-21**

Expiry Date: **2026-07-20**

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Page 3 of 10

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A Member of the BSI Group of Companies.

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 735821 R000

Intended Purpose as per the Instructions for Use: These Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients who are at risk for sudden cardiac death caused by ventricular arrhythmias and who have heart failure (including asymptomatic [NYHA Class I] ischemic heart failure) with ventricular dyssynchrony.

Risk Classification: Class III Implantable

Type (Codes as per (EU) 2017/2185): MDA 0101

Basic UDI-DI: 0191506000000000000083MW

RESONATE Family of CRT-Ds			
Device Name	Model Number	Connector Type	MR Conditional
RESONATE HF CRT-D	G524	RA: IS-1, RV: DF4, LV: IS-1	Yes
	G525	RA: IS-1, RV: IS-1/DF-1, LV: IS-1	Yes
	G526	RA: IS-1, RV: IS-1/DF-1, LV: LV-1	No
	G528	RA: IS-1, RV: IS-1/DF-1, LV: IS4	Yes
	G537	RA: IS-1, RV: DF4, LV: IS4	Yes
	G547	RA: IS-1, RV: DF4, LV: IS4	Yes
	G548	RA: IS-1, RV: IS-1/DF-1, LV: IS4	Yes
RESONATE CRT-D	G424	RA: IS-1, RV: DF4, LV: IS-1	Yes
	G425	RA: IS-1, RV: IS-1/DF-1, LV: IS-1	Yes
	G426	RA: IS-1, RV: IS-1/DF-1, LV: LV-1	No
RESONATE X4 CRT-D	G428	RA: IS-1, RV: IS-1/DF-1, LV: IS4	Yes
	G437	RA: IS-1, RV: DF4, LV: IS4	Yes
	G447	RA: IS-1, RV: DF4, LV: IS4	Yes
	G448	RA: IS-1, RV: IS-1/DF-1, LV: IS4	Yes

First Issued: **2021-07-21**

Date: **2021-07-21**

Expiry Date: **2026-07-20**

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Page 4 of 10

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 735821 R000

RESONATE Family of CRT-Ds			
Device Name	Model Number	Connector Type	MR Conditional
MOMENTUM CRT-D	G124	RA: IS-1, RV: DF4, LV: IS-1	Yes
	G125	RA: IS-1, RV: IS-1/DF-1, LV: IS-1	Yes
	G126	RA: IS-1, RV: IS-1/DF-1, LV: LV-1	No
MOMENTUM X4 CRT-D	G128	RA: IS-1, RV: IS-1/DF-1, LV: IS4	Yes
	G138	RA: IS-1, RV: IS-1/DF-1, LV: IS4	Yes
CHARISMA CRT-D	G324	RA: IS-1, RV: DF4, LV: IS-1	Yes
	G325	RA: IS-1, RV: IS-1/DF-1, LV: IS-1	Yes
CHARISMA X4 CRT-D	G328	RA: IS-1, RV: IS-1/DF-1, LV: IS4	Yes
	G337	RA: IS-1, RV: DF4, LV: IS4	Yes
	G347	RA: IS-1, RV: DF4, LV: IS4	Yes
	G348	RA: IS-1, RV: IS-1/DF-1, LV: IS4	Yes
VIGILANT CRT-D	G224	RA: IS-1, RV: DF4, LV: IS-1	Yes
	G225	RA: IS-1, RV: IS-1/DF-1, LV: IS-1	Yes
VIGILANT X4 CRT-D	G228	RA: IS-1, RV: IS-1/DF-1, LV: IS4	Yes
	G237	RA: IS-1, RV: DF4, LV: IS4	Yes
	G247	RA: IS-1, RV: DF4, LV: IS4	Yes
	G248	RA: IS-1, RV: IS-1/DF-1, LV: IS4	Yes

Additional Information: All CRT-Ds contain the extended longevity (EL) battery.

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 735821 R000

Intended Purpose as per the Instructions for Use: Boston Scientific implantable cardioverter defibrillators (ICDs) are intended to provide ventricular antitachycardia pacing (ATP) and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

Risk Classification: Class III Implantable

Type (Codes as per (EU) 2017/2185): MDA 0101

Basic UDI-DI: 0191506000000000000084MY

AUTOGEN Family of ICDs

Device Name	Model Number	Connector Type	VR or DR	MR Conditional
AUTOGEN EL ICD	D174	RV: DF4	VR	Yes
	D175	RV: IS-1/DF-1	VR	Yes
	D176	RA: IS-1, RV: DF4	DR	Yes
	D177	RA: IS-1, RV: IS-1/DF-1	DR	Yes
AUTOGEN MINI ICD	D044	RV: DF4	VR	Yes
	D045	RV: IS-1/DF-1	VR	Yes
	D046	RA: IS-1, RV: DF4	DR	Yes
	D047	RA: IS-1, RV: IS-1/DF-1	DR	Yes
DYNAGEN EL ICD	D150	RV: DF4	VR	Yes
	D151	RV: IS-1/DF-1	VR	Yes
	D152	RA: IS-1, RV: DF4	DR	Yes
	D153	RA: IS-1, RV: IS-1/DF-1	DR	Yes

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AUTOGEN Family of ICDs				
Device Name	Model Number	Connector Type	VR or DR	MR Conditional
DYNAGEN MINI ICD	D020	RV: DF4	VR	Yes
	D021	RV: IS-1/DF-1	VR	Yes
	D022	RA: IS-1, RV: DF4	DR	Yes
	D023	RA: IS-1, RV: IS-1/DF-1	DR	Yes
INOGEN EL ICD	D140	RV: DF4	VR	Yes
	D141	RV: IS-1/DF-1	VR	Yes
	D142	RA: IS-1, RV: DF4	DR	Yes
	D143	RA: IS-1, RV: IS-1/DF-1	DR	Yes
INOGEN MINI ICD	D010	RV: DF4	VR	Yes
	D011	RV: IS-1/DF-1	VR	Yes
	D012	RA: IS-1, RV: DF4	DR	Yes
	D013	RA: IS-1, RV: IS-1/DF-1	DR	Yes
ORIGEN EL ICD	D050	RV: DF4	VR	Yes
	D051	RV: IS-1/DF-1	VR	Yes
	D052	RA: IS-1, RV: DF4	DR	Yes
	D053	RA: IS-1, RV: IS-1/DF-1	DR	Yes
ORIGEN MINI ICD	D000	RV: DF4	VR	Yes
	D001	RV: IS-1/DF-1	VR	Yes
	D002	RA: IS-1, RV: DF4	DR	Yes
	D003	RA: IS-1, RV: IS-1/DF-1	DR	Yes

Additional Information: The MINI ICDs contain the standard longevity (SL) battery. All other ICDs contain the extended longevity (EL) battery.

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Intended Purpose as per the Instructions for Use: These Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients who are at risk for sudden cardiac death caused by ventricular arrhythmias and who have heart failure (including asymptomatic [NYHA Class I] ischemic heart failure) with ventricular dyssynchrony.

Risk Classification: Class III Implantable

Type (Codes as per (EU) 2017/2185): MDA 0101

Basic UDI-DI: 0191506000000000000083MW

AUTOGEN Family of CRT-Ds			
Device Name	Model	Connector Type	MR Conditional
AUTOGEN CRT-D	G172	RA: IS-1, RV: DF4, LV: IS-1	Yes
	G173	RA: IS-1, RV: IS-1/DF-1, LV: IS-1	Yes
	G175	RA: IS-1, RV: IS-1/DF-1, LV: LV-1	No
AUTOGEN X4 CRT-D	G177	RA: IS-1, RV: IS-1/DF-1, LV: IS4	Yes
	G179	RA: IS-1, RV: DF4, LV: IS4	Yes
DYNAGEN CRT-D	G150	RA: IS-1, RV: DF4, LV: IS-1	Yes
	G151	RA: IS-1, RV: IS-1/DF-1, LV: IS-1	Yes
DYNAGEN X4 CRT-D	G156	RA: IS-1, RV: IS-1/DF-1, LV: IS4	Yes
	G158	RA: IS-1, RV: DF4, LV: IS4	Yes
INOGEN CRT-D	G140	RA: IS-1, RV: DF4, LV: IS-1	Yes
	G141	RA: IS-1, RV: IS-1/DF-1, LV: IS-1	Yes
INOGEN X4 CRT-D	G146	RA: IS-1, RV: IS-1/DF-1, LV: IS4	Yes
	G148	RA: IS-1, RV: DF4, LV: IS4	Yes
ORIGEN CRT-D	G050	RA: IS-1, RV: DF4, LV: IS-1	Yes
	G051	RA: IS-1, RV: IS-1/DF-1, LV: IS-1	Yes
ORIGEN X4 CRT-D	G056	RA: IS-1, RV: IS-1/DF-1, LV: IS4	Yes
	G058	RA: IS-1, RV: DF4, LV: IS4	Yes

Additional Information: All CRT-Ds contain the extended longevity (EL) battery.

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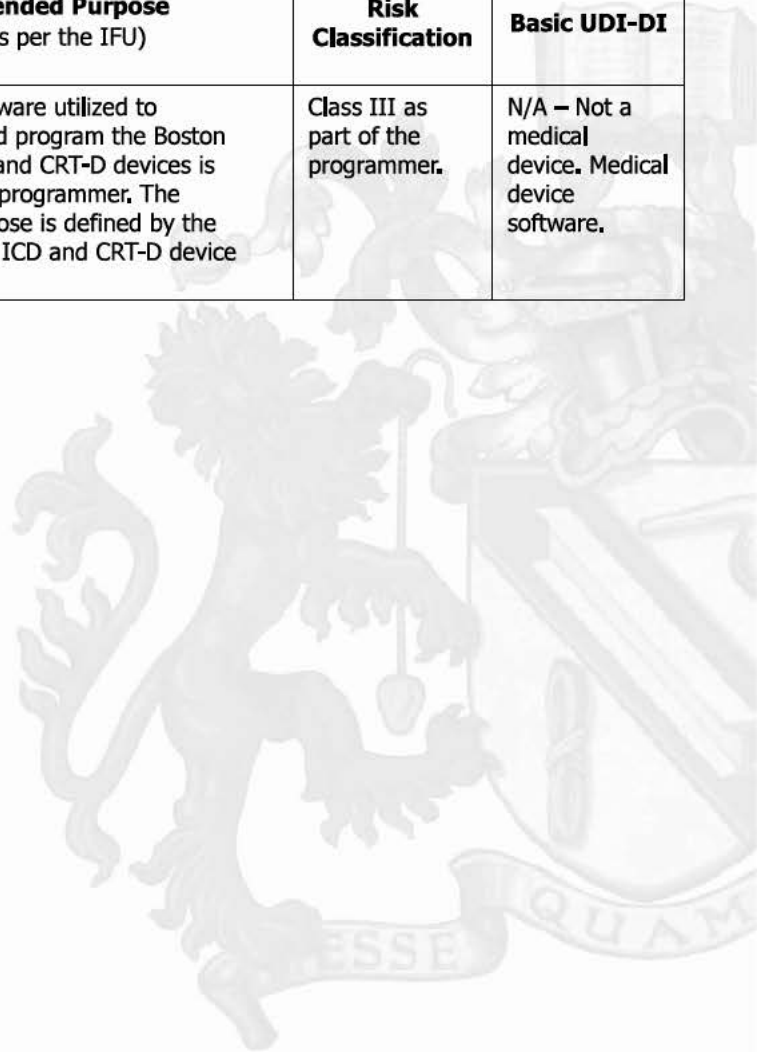
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Device Name	Model	Type (Codes as per (EU) 2017/2185)	Intended Purpose (as per the IFU)	Risk Classification	Basic UDI-DI
Application software for Model 3300 LATITUDE Programming System.	3868	MDA 0101	N/A - The software utilized to interrogate and program the Boston Scientific ICD and CRT-D devices is loaded on the programmer. The Intended Purpose is defined by the corresponding ICD and CRT-D device tables above.	Class III as part of the programmer.	N/A – Not a medical device. Medical device software.

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3283734	Issued

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