

EU Technical Documentation Assessment Certificate

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

MDR 733839 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-000010933

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):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2021-12-13**

Date: **2021-12-13**

Expiry Date: **2026-12-12**

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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
INGEVITY MRI Tined Fixation Lead	7731 7732	MDA0101	Intended for chronic pacing and sensing in the right atrium (Preformed Atrial J) or right ventricle (Straight) when used with a compatible pulse generator.	Class III, Implantable	01915060000000000000 0085N2
INGEVITY MRI Tined Fixation Lead	7735 7736	MDA0101		Class III, Implantable	
INGEVITY MRI Extendable/ Retractable Fixation Lead	7740 7741 7742	MDA0101	Intended for chronic pacing and sensing in the right atrium and/or right ventricle when used with a compatible pulse generator.	Class III, Implantable	01915060000000000000 0086N4
INGEVITY+ Lead	7840 7841 7842	MDA0101		Class III, Implantable	01915060000000000000 0087N6
Suture Sleeve, Attachable	6402	MDA0101	Use to secure and immobilize Boston Scientific INGEVITY™ leads at the venous entry site. This accessory suture sleeve is intended to be used as a replacement for the pre-loaded suture sleeve in the event of damage or loss.	Class III, Implantable	01915060000000000000 0088N8

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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	3269288	Issued



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