# Certificate

## Design Examination

**No. CE 566332**

Issued to:

**Cardiac Pacemakers Incorporated**
**a wholly owned subsidiary of Guidant Corporation**
**a wholly owned subsidiary of Boston Scientific Corporation**
**4100 Hamline Avenue North**
**Saint Paul**
**Minnesota 55112-5798**
**USA**

In respect of:

**Implantable Cardioverter Defibrillators:**
**INCEPTA CRT-D Family, INCEPTA ICD Family, ENERGEN CRT-D Family, ENERGEN ICD Family, PUNCTUA and PUNCTUA NE CRT-D Family, PUNCTUA and PUNCTUA NE ICD Family**

on the basis of our examination under the requirements of Council Directive 90/385/EEC, Annex 2, Section 4.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Gary Fenton, Global Assurance Director

First Issued: **6 Oct 2010** Date: **15 Feb 2012**

Expiration Date: **5 Oct 2015**



*Conditions of Approval*
Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive.

*raising standards worldwide™*

**Information and Contact:** BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: +44 (0)845 080 9000

# Certificate

## Supplementary Information to CE 566332

Issued to:
**Cardiac Pacemakers Incorporated**
**a wholly owned subsidiary of Guidant Corporation**
**a wholly owned subsidiary of Boston Scientific Corporation**
**Minnesota 55112-5798**
**USA**

| Product Description | Model Number |
|---|---|
| INCEPTA™ ICD | F160, F161, F162, F163, E160*, E161*, E162*, E163* |
| INCEPTA™ CRT-D | P162, P163, P165, N162*, N163*, N165* |
| ENERGEN™ ICD | F140, F141, F142, F143, E140*, E141*, E142*, E143* |
| ENERGEN™ CRT-D | P142, P143, N142*, N143* |
| PUNCTUA™ ICD | F050, F052, E050*, E052*, E051*, E053* |
| PUNCTUA™ NE ICD | F051, F053 |
| PUNCTUA™ CRT-D | P052, N052*, N053* |
| PUNCTUA™ NE CRT-D | P053 |
| Application Software | 2868 |
| Torque Wrench | 6628 |

*E and N models employ a non-harmonised telemetry frequency for use outside the EEA.

First Issued: **6 Oct 2010**
Expiration Date: **5 Oct 2015**

Date: **15 Feb 2012**



*raising standards worldwide™*

# Certificate

# Supplementary Information to CE 566332

Issued to:
**Cardiac Pacemakers Incorporated**
**a wholly owned subsidiary of Guidant Corporation**
**a wholly owned subsidiary of Boston Scientific Corporation**
**Minnesota 55112-5798**
**USA**

## History of Certificate

| Date | Customer Reference | Action |
|---|---|---|
| 06 October 2010 | 10117686 | First issue – including Application Software Model 2868 Version 2.03 and pulse generator embedded software Version B_v1.02.00 |
| 23 March 2011 | 10121173 | Addendum – Addition of the MADIT CRT-D indication to the INCEPTA™ CRT-D Models - P162, P163, P165, NI62*, NI63* and N165*; ENERGEN™ CRT-D Models - P142, P143, NI42* and N143*; PUNCTUA™ CRT-D Models - P052, N052*and N053*; PUNCTUA™ NE CRT-D Model - P053. Corresponding change to the Physician Technical Manual. |
| 11 April 2011 | 10123414 | Addendum - Modification of pulse generator embedded software from version B_v1.02.00 to B_v1.02.00, Patch_v1.01. Modification of Application Software Model 2868 from version 2.03 to 2.04. Manufacturing process and equipment changes for E-clip insertion. |
| 28 September 2011 | 10130407 | Addendum – Design changes to feedthru. Boston Scientific to manufacture unfiltered feedthru internally as an alternate source to the current supplier. Modifications to Super Output Module. Varioprint added as alternate source supplier of motherboard PCB. U103 Resistor Array R5 modification and addition of AVX as alternate source supplier. |
| 15 February 2012 | 10133540 | Addendum - Design change to spot weld anchor post. |

First Issued: **6 Oct 2010** Date: **15 Feb 2012**

Expiration Date: **5 Oct 2015**



*raising standards worldwide™*

Boston Scientific

# EC - Declaration of Conformity

**We, Cardiac Pacemakers Inc.,**
**A wholly owned subsidiary of Guidant Corporation**
**A wholly owned subsidiary of Boston Scientific Corporation**

**Manufacturer's Address**

4100 Hamline Avenue North
Saint Paul, Minnesota 55112 USA

**EU Authorized Representative Address**

Guidant Europe NV/SA
Green Square; Lambroekstraat 5D
B-1831 Diegem
Belgium

**being the manufacturer/distributor within the European Economic Area of the following products:**

**INCEPTA™ ICD Models – F160, F161, F162, F163, E160*, E161*, E162*, E163***
**INCEPTA™ CRT-D Models – P162, P163, P165, N162*, N163*, N165***
**ENERGEN™ ICD Models - F140, F141, F142, F143, E140*, E141*, E142*, E143***
**ENERGEN™ CRT-D Models - P142, P143, N142*, N143***
**PUNCTUA™ ICD Models – F050, F052, E050*, E052*, E051*, E053***
**PUNCTUA™ NE ICD Models – F051, F053**
**PUNCTUA™ CRT-D Models – P052, N052*, N053***
**PUNCTUA™ NE CRT-D Model – P053**
**Model 2868 Software Application Version 2.04**
**Bi-directional Torque Wrench Model 6628**

**declare that the above listed products are in conformity with the applicable European Member State laws implementing the**

**Active Implantable Medical Devices Directive (90/385/EEC)**
**Annex I: Essential Requirements**
**and have been subject to the conformity assessment procedures as laid down in**
**Annex II: Quality Assurance System**

**under the supervision of the British Standards Institution, a Notified Body authorized by the United Kingdom Competent Authority, and carrying the Notified Body Number 0086.**

**Declaration for CE 566332 issued on: 15 Feb 2012**

**Kristen Harty, Director of Regulatory Affairs**

**Steven C de Baca, Vice President Quality Assurance**

**Dan Goldman, Vice President Research and Development**