



## 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):

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Gary Fenton, Global Assurance Director

First Issued: 6 Oct 2010

Date: 15 Feb 2012

Expiration Date: 5 Oct 2015

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*Conditions of Approval*

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

## Supplementary Information to CE 566332

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**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.

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### 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.

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# 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

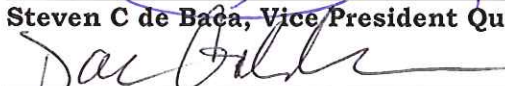
and have been subject to the conformity assessment procedures as laid down in Annex II: Quality Assurance System

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

  
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Kristen Harty, Director of Regulatory Affairs

  
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Steven C de Baca, Vice President Quality Assurance

  
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Dan Goldman, Vice President Research and Development