

**bsi.**



Certificate

# Design Examination

**No. CE 534263**



Issued to:

**Abbott Vascular  
3200 Lakeside Drive  
Santa Clara  
California  
95054  
USA**

In respect of:

**HI-TORQUE BALANCE MIDDLEWEIGHT UNIVERSAL II Guide Wires**

On the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex II, 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: **18 Feb 2008**

Date: **2 Jul 2013**

Expiration Date: **17 Feb 2018**

Page: 1 of 3

*Conditions of Approval*

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

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# Supplementary Information to CE 534263

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**Abbott Vascular**  
**Santa Clara**  
**USA**

<b>Catalogue Number</b>	<b>Description</b>
1009664	190cm, Straight Tip Shape, with markers
1009664J	190cm, 'J' Tip Shape, with markers
1009665	300cm, Straight Tip Shape, with markers
1009665J	300cm, 'J' Tip Shape, with markers
1009666	190cm, Straight Tip Shape, without markers
1009666J	190cm, 'J' Tip Shape, without markers
1009667	300cm, Straight Tip Shape, without markers
1009667J	300cm, 'J' Tip Shape, without markers

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Page: 2 of 3

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## History to Certificate

Date	Reference Number	Action
18 February 2008	10093095	Initial issue
16 October 2009	10110051	Addition of manufacturing site in Barceloneta, Puerto Rico for Hi-Torque Balance Middleweight Universal II Guide Wires. Remove Cardiac Therapies division from company name.
12 September 2012	10136292	Addition of alternative Teflon Coating.
15 February 2013	10140455	Certificate renewal.
07 June 2013	10141132	Addition of Synergy Health-Tullamore, Ireland as a qualified sterilization site.
02 July 2013	10132172	Addition of AIOx/Foil peel-able pouch as alternate

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Page: 3 of 3

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