Certificate

Design Examination

No. CE 60607

Issued to:

Abbott Vascular
3200 Lakeside Drive
Santa Clara, California 95054
USA

In respect of:
MULTI-LINK RX ZETA™ AND MULTI-LINK OTW ZETA™ Coronary Stent Systems

On the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex II, Section 4.

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

David Ford, Director, Healthcare and Testing Services

First Issued: **15 Apr 2002** Date: **9 Nov 2009**

Expiration Date: **14 Apr 2012**

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 60607

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MULTI-LINK RX ZETA™ Coronary Stent System

1009836-08	1009836-13	1009836-15	1009836-18
1009836-23	1009836-28	1009837-08	1009837-13
1009837-15	1009837-18	1009837-23	1009837-28
1009838-08	1009838-13	1009838-15	1009838-18
1009838-23	1009838-28	1009838-33	1009838-38
1009839-08	1009839-13	1009839-15	1009839-18
1009839-23	1009839-28	1009839-33	1009839-38
1009840-08	1009840-13	1009840-15	1009840-18
1009840-23	1009840-28	1009840-33	1009840-38

MULTI-LINK OTW ZETA™ Coronary Stent System

1009856-08	1009856-13	1009856-15	1009856-18
1009856-23	1009856-28	1009857-08	1009857-13
1009857-15	1009857-18	1009857-23	1009857-28
1009858-08	1009858-13	1009858-15	1009858-18
1009858-23	1009858-28	1009858-33	1009858-38
1009859-08	1009859-13	1009859-15	1009859-18
1009859-23	1009859-28	1009859-33	1009859-38
1009860-08	1009860-13	1009860-15	1009860-18
1009860-23	1009860-28	1009860-33	1009860-38

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History of Certificate

Date	Reference Number	Action
15 April 2002	10035924	Original Issue
20 May 2003	10050519	Reissue following notification to extend product shelf life to 2 years
27 June 2003	10050781	Minor modification to junction sleeve
21 November 2003	10050302	Amendment to Indications for Use of Multilink family of stents
04 March 2004	10055842	Approval of Guidant Ireland for Electron beam sterilization
04 July 2005	10068865	Extension of shelf life to 3 years
01 August 2006	10080118	Change to company name
30 March 2007	10087751	Renewal
30 June 2008	10096966	Review of mold release change in molded catheter components
09 November 2009	10110241	Remove Cardiac Therapies division from company name

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