EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

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

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2008-02-18** Date: **2020-03-25** Expiry Date: **2023-02-17**

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Supplementary Information to CE 534263

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Catalogue Number	Description
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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Certificate History

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 sterilizatiion site.
02 July 2013	10132172	Addition of AIOx/Foil peel-able pouch as alternate.
05 October 2015	10158710	Change review to assess the impact of the Loctite 648 reformulation.

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Date	Reference Number	Action
16 June 2016	10163340	Addition of Synergy Health in Costa Rica as an alternate sterilization site for E-beam services.
04 December 2016	10167240	Addition of alternate AIOx/Foil peel pouch with different film layer.
09 February 2018	8892812	Certificate renewal.
27 February 2019	7780598	Traceable to NB 0086.
Current	9772876	Introduction of alternate AlOx/Foil peel pouch design with thicker PET layer.

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