

EC Design-Examination Certificate

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

No. **CE 01497**
Issued To: **Abbott Vascular**
3200 Lakeside Drive
Santa Clara
California
95054
USA

In respect of:

HI TORQUE® 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 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **15 January 1997**

Date: **12 January 2016**

Expiry Date: **14 January 2017**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

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EC Design-Examination Certificate

Supplementary Information to CE 01497

Issued To: **Abbott Vascular
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Product: HI-TORQUE® Guide Wires

HI-TORQUE® FLOPPY II 0.014" Guide Wire

2233XM	Straight Tip Shape
2233XMJ	'J' Tip Shape
2233XM-XXX	Straight Tip Shape
2233XMJ-XXX	'J' Tip Shape
2235XM	Straight Tip Shape
2235XM-XXX	Straight Tip Shape
2235XMJ	'J' Tip Shape
2235XMJ-XXX	'J' Tip Shape

HI-TORQUE® STANDARD and INTERMEDIATE 0.014" Guide Wires

2231XM	Straight Tip Shape
2231XMJ	'J' Tip Shape
2231XM-XXX	Straight Tip Shape
2231XMJ-XXX	'J' Tip Shape
2232XM-XXX	Straight Tip Shape

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Product: **HI-TORQUE® Guide Wires**

HI-TORQUE® TRAVERSE 0.014" Guide Wire

2234XM	Straight Tip Shape
2234XMJ	'J' Tip Shape
2234XM-XXX	Straight Tip Shape
2234XMJ-XXX	'J' Tip Shape
2237XM	Straight Tip Shape
2237XMJ	'J' Tip Shape
2237XM-XXX	Straight Tip Shape
2237XMJ-XXX	'J' Tip Shape

HI-TORQUE® BALANCE 0.014" Guide Wire

2800X	Straight Tip Shape
2800XJ	'J' Tip Shape
2810X	Straight Tip Shape
2810XJ	'J' Tip Shape

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Product: HI-TORQUE® Guide Wires

HI-TORQUE® EXTRA S'PORT™ 0.014" Guide Wire

2222XM	Straight Tip Shape
2222XMJ	'J' Tip Shape
2223XM	Straight Tip Shape
2223XMJ	'J' Tip Shape
22225M-DCA	Straight Tip Shape
22235M-DCA	Straight Tip Shape
11125M-DCA	Straight Tip Shape
11135M-DCA	Straight Tip Shape

HI-TORQUE® FLOPPY II 0.014" EXTRA SUPPORT Guide Wire

2229XM	Straight Tip Shape
2229XM-XXX	Straight Tip Shape
2229XMJ-XXX	'J' Tip Shape
2235XM-XXX	Straight Tip Shape
2235XMJ-XXX	'J' Tip Shape
2239XM	Straight Tip Shape

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Product: HI-TORQUE® Guide Wires

HI-TORQUE® IRONMAN 0.014" Guide Wire

100130X	Straight Tip Shape
100130XJ	'J' Tip Shape
100131X	Straight Tip Shape
100131XJ	'J' Tip Shape

HI-TORQUE® BALANCE MIDDLEWEIGHT™ 0.014" Guide Wire

1001780	Straight Tip Shape
1001780J	'J' Tip Shape
1001781	Straight Tip Shape
1001781J	'J' Tip Shape
1001782	Straight Tip Shape
1001782J	'J' Tip Shape
1001783	Straight Tip Shape
1001783J	'J' Tip Shape
666720-200	Straight Tip Shape

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Product: **HI-TORQUE® Guide Wires**

HI-TORQUE® ALL STAR™ 0.014" Guide Wire

1001740	Straight Tip Shape
1001740J	'J' Tip Shape
1001741	Straight Tip Shape
1001741J	'J' Tip Shape

HI-TORQUE® WIGGLE™ Guide Wire with MICROGLIDE® Coating

2229XM-W2	Straight Tip Shape
2229XM-W30	Straight Tip Shape
2235XM-W2	Straight Tip Shape
2239XM-W30	Straight Tip Shape

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Date	Reference Number	Action
15 January 1997	MD 000188	First Issue
14 March 1997	MD 000215	ACS HI-TORQUE® IRON MAN Guide Wire added to product listing
17 June 1997	MD 000234	ACS HI-TORQUE® BALANCE MIDDLEWEIGHT™ Guide Wires added to product listing
12 August 1997	MD 000244	ACS HI-TORQUE® RULER™ Guide Wires added to product listing
3 November 1997	MD 000266	ACS HI-TORQUE® ALL STAR™ .014" Guide Wire with Microglide® Coating added to product listing
19 May 1998	MD 000367	ACS HI-TORQUE® SUPRA CORE™ 35 Guide Wires added to product listing
20 May 1998	MD 000399	ACS HI-TORQUE® CROSS-IT™ Guide Wires with HYDROCOAT™ Hydrophilic Coating added to product listing
27 August 1998	MD 000374	ACS HI-TORQUE® SUPER S'PORT™ Guide Wires with HYDROCOAT™ Hydrophilic Coating added to the product listing
27 October 1998	MD 000478	Modification to ACS HI-TORQUE® BALANCE MIDDLEWEIGHT™ Guide Wire IFU to include additional indications for placement and support for both arterial and Venous locations
13 November 1998	MD 000472	ACS HI-TORQUE® STEELCORE™ 18 Guide Wires added to product listing and modifications to the ACS HI-TORQUE® IRONCORE™ Guide Wire involving modifying the length and marker location

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Date	Reference Number	Action
13 November 1998	MD 000474	Modifications to the ACS HI-TORQUE® MEMCORE™ involving modifying the length and marker location
11 February 1999	MD 000476	Modifications to the ACS HI-TORQUE® BALANCE MIDDLEWEIGHT™ Guide Wire with modified intended use reference number correction
24 March 1999	MD 000559	ACS HI-TORQUE® CROSS-IT™ 100XT, 200XT, 300XT AND 400XT Guide Wires with HYDROCOAT™ Hydrophilic Coating added to product listing
12 May 1999	MD 000540	ACS HI-TORQUE® WIGGLE™ Guide Wires with Microglide® Coating added to product listing
14 May 1999	MD 000578	HI-TORQUE® SPARTACORE™ 14 Guide Wires added to product listing
17 February 2000	MD 000638	Electron beam irradiation added as an additional means of sterilization
26 June 2000	EQ 1001 5688	HI-TORQUE® STEELCORE™ 18 LT Guide Wires added to product listing
19 September 2000	EQ 1001 7711	HI-TORQUE® EXTRA S'PORT™ 0.014 Guide Wires modified to extend the PTFE coating and additional 22cm on the distal portion of the core wire

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Date	Reference Number	Action
20 August 2002	EQ 1004 1783	Certificate renewal
22 June 2005	EQ 1006 9047	HI-TORQUE® MEMCORE™, SUPRACORE™, STEELCORE™ 18 and 18LT and SPARTACORE™ removed from product listings. History page added to certificate
01 August 2006	EQ 1008 0118	Change of company name
19 March 2007	EQ 1008 2964	Certificate renewal
09 November 2009	EQ 1011 0241	Remove Cardiac Therapies division from company name.
13 December 2011	EQ 10130228	Certificate renewal
12 September 2012	EQ 10136292	Addition of alternative Teflon Coating.
07 June 2013	10141132	Addition of Synergy Health-Tullamore, Ireland as a qualified sterilization site
10 August 2014	10149802	Transfer of manufacturing from the Abbott Vascular Murrieta facility to the Abbott Vascular Temecula facility.
05 October 2015	10158710	Change review to assess the impact of the Loctite 648 reformulation.
12 January 2016	10159718	DuPont Tyvek Medical Transition Project update.

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