

# EC Design-Examination Certificate

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

**No.** **CE 01753**  
**Issued To:** **Abbott Vascular**  
**3200 Lakeside Drive**  
**Santa Clara**  
**California**  
**95054**  
**USA**

In respect of:

**HI-TORQUE® Guide Wires with Hydrocoat Hydrophilic Coating and**  
**HI-TORQUE® Guide Wires with Hydrophilic Coating**

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: **04 November 1997**

Date: **12 January 2016**

Expiry Date: **03 November 2017**

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# EC Design-Examination Certificate

## Supplementary Information to CE 01753

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### Product: **HI-TORQUE® Guide Wires with Hydrocoat Hydrophilic Coating**

#### HI-TORQUE® FLOPPY II® 0.014" Guide Wire with Hydrocoat Hydrophilic Coating

223X9H	Straight Tip Shape
223X9HJ	'J' Tip Shape
223X9H-XXX	Straight Tip Shape
223X9HJ-XXX	'J' Tip Shape

#### HI-TORQUE® STANDARD® 0.014" Guide Wire with Hydrocoat Hydrophilic Coating

2231XH	Straight Tip Shape
2231XJH	'J' Tip Shape
223XXH-XXX	Straight Tip Shape
223XXHJ-XXX	'J' Tip Shape

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### Product: **HI-TORQUE® Guide Wires with Hydrocoat Hydrophilic Coating**

#### HI-TORQUE® INTERMEDIATE® 0.014" Guide Wire with Hydrocoat Hydrophilic Coating

22317H	Straight Tip Shape
22317HJ	'J' Tip Shape
22317H-XXX	Straight Tip Shape
22317HJ-XXX	'J' Tip Shape

#### HI-TORQUE® TRAVERSE® 0.014" Guide Wire with Hydrocoat Hydrophilic Coating

223X9H	Straight Tip Shape
223X9HJ	'J' Tip Shape
223X9H-XXX	Straight Tip Shape
223X9HJ-XXX	'J' Tip Shape

#### HI-TORQUE® BALANCE® 0.014" Guide Wire with Hydrocoat Hydrophilic Coating

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

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### Product: **HI-TORQUE® Guide Wires with Hydrocoat Hydrophilic Coating**

#### HI-TORQUE® FLOPPY II® 0.014" EXTRA SUPPORT Guide Wire with Hydrocoat Hydrophilic Coating

22X99H	Straight Tip Shape
22X99H-XXX	Straight Tip Shape
22X99HJ-XXX	'J' Tip Shape
223X9H-XXX	Straight Tip Shape
223X9HJ-XXX	'J' Tip Shape

#### HI-TORQUE® BALANCE MIDDLEWEIGHT™ 0.014" Guide Wire with Hydrocoat Hydrophilic Coating

100178X-HC	Straight Tip Shape
100178XJ-HC	'J' Tip Shape

#### HI-TORQUE® BALANCE HEAVYWEIGHT™ 0.014" Guide Wire with Hydrocoat Hydrophilic Coating

1000460H	Straight Tip Shape
1000460HJ	'J' Tip Shape
1000462H	Straight Tip Shape
1000462HJ	'J' Tip Shape
1000463H	Straight Tip Shape
1000463HJ	'J' Tip Shape

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### Product: **HI-TORQUE® Guide Wires with Hydrocoat Hydrophilic Coating**

#### HI-TORQUE® BALANCE TREK™ 0.014" Guide Wire with Hydrocoat Hydrophilic Coating

100515XH	Straight Tip Shape
100515XHJ	'J' Tip Shape
100516XH	Straight Tip Shape
100516XHJ	'J' Tip Shape

#### HI-TORQUE® CROSS-IT™ 100XT Guide Wire with Hydrocoat Hydrophilic Coating

10033XXH	Straight Tip Shape
10033XXHJ	'J' Tip Shape

#### HI-TORQUE® CROSS-IT™ 200XT Guide Wire with Hydrocoat Hydrophilic Coating

10033XXH	Straight Tip Shape
10033XXHJ	'J' Tip Shape

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### Product: **HI-TORQUE® Guide Wires with Hydrocoat Hydrophilic Coating**

#### HI-TORQUE® CROSS-IT™ 300XT Guide Wire with Hydrocoat Hydrophilic Coating

10033XXH	Straight Tip Shape
10033XXHJ	'J' Tip Shape

#### HI-TORQUE® CROSS-IT™ 400XT Guide Wire with Hydrocoat Hydrophilic Coating

10033XXH	Straight Tip Shape
10033XXHJ	'J' Tip Shape

#### HI-TORQUE® FLEXI-WIRE™ Guide Wire with Hydrocoat Hydrophilic Coating

1008122	1008124
1008123	1008125

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### Product: HI-TORQUE® Guide Wires with Hydrophilic Coating

#### HI-TORQUE® WHISPER™ LS 0.014" Guide Wire with Hydrophilic Coating

Catalogue Number	Device Length	Tip Shape	Radiopaque Length
1005349H	175 cm	Straight	3 cm
1005349HJ	175 cm	`J'	3 cm
1005351H	190 cm	Straight	3 cm
1005351HJ	190 cm	`J'	3 cm
1005353H	300 cm	Straight	3 cm
1005353HJ	300 cm	`J'	3 cm

#### HI-TORQUE® WHISPER™ MS 0.014" Guide Wire with Hydrophilic Coating

Catalogue Number	Device Length	Tip Shape	Radiopaque Length
1005355H	175 cm	Straight	3 cm
1005355HJ	175 cm	`J'	3 cm
1005357H	190 cm	Straight	3 cm
1005357HJ	190 cm	`J'	3 cm
1005359H	300 cm	Straight	3 cm
1005359HJ	300 cm	`J'	3 cm

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### Product: HI-TORQUE® Guide Wires with Hydrophilic Coating

#### HI-TORQUE® WHISPER™ EXTRA SUPPORT 0.014" Guide Wire with Hydrophilic Coating

Catalogue Number	Device Length (cm)	Tip shape	Radiopaque Length (cm)
1011834H	190	straight	3.0 cm
1011834HJ	190	J	3.0 cm
1011835H	300	straight	3.0 cm
1011835HJ	300	J	3.0 cm

#### HI-TORQUE® BALANCE MIDDLEWEIGHT UNIVERSAL Guide Wires with Hydrophilic Coating

1009659	1009660
1009661	1009659J
1009660J	1009661J

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## Certificate History

Date	Reference Number	Action
4 November 1997	MD000308	Initial issue
17 August 1998	MD000473	ACS HI-TORQUE® BALANCE HEAVYWEIGHT™ 0.014" Guide Wire with Hydrocoat Hydrophilic coating name changed to ACS HI-TORQUE® MEMCORE FIRM™ 0.014" Guide Wire with Hydrocoat Hydrophilic coating
4 May 1999	MD000579	HI-TORQUE® BALANCE TREK™ Guide Wires added to product listings
13 May 1999	MD000638	Electron-beam irradiation added as an additional means of sterilization
31 January 2000	EQ10009807	EtO masterfile updated
05 May 2000	EQ10010347	Change of coating to Hydrphilic coating
11 September 2000	EQ10015026	Method of sterilization changed from EtO to E-beam
19 December 2000	EQ 10017683	Change to the design of HI-TORQUE® EXTRA S'PORT™ 0.014" Guide Wire with Hydrocoat Hydrophilic coating
5 December 2001	EQ10032120	HI-TORQUE® BALANCE MIDDLEWEIGHT UNIVERSAL™ Guide Wires added to product listing
11 February 2002	EQ10032991	Shelf life extended to 2 years
3 January 2003	EQ 10045605	Certificate Renewal

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Date	Reference Number	Action
20 February 2003	EQ10047931	Correction to shelf-life claims
27 October 2003	EQ 10050515	HI-TORQUE® BALANCE UNIVERSAL™ Guide Wire with Hydrocoat Hydrophilic coating added to the scope
22 June 2005	EQ 10069075	History page added to the certificate
01 August 2006	EQ 10080118	Change to company name
29 June 2007	EQ 10087940	HI-TORQUE® WHISPER™EXTRA SUPPORT 0.014" Guide Wire with HYDROCOAT Hydrophilic Coating line extension
22 November 2007	EQ 10092472	Certificate renewal and corrections to model numbers for the Hi-Torque Iron Man 0.014" and Hi-Torque Balance Middleweight 0.014" Guide Wires.
16 October 2009	EQ 10110051	Addition of manufacturing site in Barceloneta, Puerto Rico for Hi-Torque Balance Middleweight Universal Guide Wire with Hydrocoat Hydrophilic Coating. Remove Cardiac Therapies division from company name.
28 June 2010	EQ 10116576	Change of coating on Hi-Torque Whisper and Balance Middleweight Universal Guide Wires.

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Date	Reference Number	Action
27 July 2011	EQ 10125088	Addition of manufacturing site in Barceloneta, Puerto Rico for the following devices: Hi-Torque Whisper LS with Hydrophilic Coating Guide Wire (length 175 cm excluded) Hi-Torque Whisper MS with Hydrophilic Coating Guide Wire (length 175 cm excluded) Hi-Torque Whisper Extra Support with Hydrophilic Coating Guide Wire
12 September 2012	EQ 10136292	Addition of alternative Teflon Coating. Correction of typographical errors.
24 October 2012	EQ 10136355	Certificate renewal and removal of products no longer manufactured and marketed.
07 June 2013	10141132	Addition of Synergy Health-Tullamore, Ireland as a qualified sterilization site.
02 July 2013	10142172	Addition of AIOx/Foil peel-able pouch as alternate
10 August 2014	10149802	Transfer of manufacturing from the Abbott Vascular Murrieta facility to the Abbott Vascular Temecula facility.

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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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