

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 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **1997-11-04**Date: **2020-03-25**Expiry Date: **2022-11-03**

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EC Design-Examination Certificate

Supplementary Information to CE 01753

Issued To:

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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
2231XHJ	'J' Tip Shape
223XXH-XXX	Straight Tip Shape
223XXHJ-XXX	'J' Tip Shape

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
 BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
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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® 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
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
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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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 Barceolneta, 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.
14 March 2016	10161601	Addition of alternate Tyvek pouch with different laminate structure.
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.
23 October 2017	8800282	Certificate renewal. Remove Hi-Torque Balance Trek Guide wire and Hi-Torque WHISPER LS/MS 0.014" 175cm Guide wire from scope.
18 December 2017	8865690	Typographical error correction.
27 February 2019	7780598	Traceable to NB 0086.
Current	9772876	Introduction of alternate AIOx/Foil peel pouch design with thicker PET layer.

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