

EC Design-Examination Certificate

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

No. **CE 616303**
Issued To: **Boston Scientific Corporation**
300 Boston Scientific Way
Marlborough
Massachusetts
01752
USA

In respect of:

ChoICE, ChoICE PT, PT Graphix, Mailman, Luge and ACUITY 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: **2014-06-30**

Date: **2021-04-09**

Expiry Date: **2024-05-26**

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Page 1 of 14

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.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, 389 Chiswick Park Avenue, Uxbridge, Middlesex, UK
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 616303

Issued To:

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough
Massachusetts
01752
USA

Product: Interventional Cardiology Guidewires

Classification: Class III

Intended Purpose per IFU: Intended to facilitate the placement of balloon dilatation catheters or other therapeutic devices during PTCA or other intravascular interventional procedures. They are not intended for use in the cerebral vasculature

Catalogue Number	Device Name	Rail Support	Length (cm)	Tip Configuration	Package Configuration
H74912132011	ChoICE Guidewire	Floppy	182	Straight	Single Pack
H7491213201J1	ChoICE Guidewire	Floppy	182	J-Tip	Single Pack
H74912132012	ChoICE Guidewire	Floppy, 182 cm	182	Straight	5 Pack
H7491213201J2	ChoICE Guidewire	Floppy, 182 cm	182	J-Tip	5 Pack
H74912116011	ChoICE Guidewire	Floppy, 300 cm	300	Straight	Single Pack
H7491211601J1	ChoICE Guidewire	Floppy, 300 cm	300	J-Tip	Single Pack
H74912116012	ChoICE Guidewire	Floppy, 300 cm	300	Straight	5 Pack
H7491211601J2	ChoICE Guidewire	Floppy, 300 cm	300	J-Tip	5 Pack
H74912135011	ChoICE Guidewire	Extra Support, 182 cm	182	Straight	Single Pack
H7491213501J1	ChoICE Guidewire	Extra Support, 182 cm	182	J-Tip	Single Pack
H74912135012	ChoICE Guidewire	Extra Support, 182 cm	182	Straight	5 Pack
H7491213501J2	ChoICE Guidewire	Extra Support, 182 cm	182	J-Tip	5 Pack
H74912119011	ChoICE Guidewire	Extra Support, 300 cm	300	Straight	Single Pack
H7491211901J1	ChoICE Guidewire	Extra Support, 300 cm	300	J-Tip	Single Pack
H74912119012	ChoICE Guidewire	Extra Support, 300 cm	300	Straight	5 Pack
H7491211901J2	ChoICE Guidewire	Extra Support, 300 cm	300	J-Tip	5 Pack

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Page 2 of 14

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
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Catalogue Number	Device Name	Rail Support	Length (cm)	Tip Configuration	Package Configuration
H74912133011	ChoICE Guidewire	Intermediate, 182 cm	182	Straight	Single Pack
H7491213301J1	ChoICE Guidewire	Intermediate, 182 cm	182	J-Tip	Single Pack
H74912133012	ChoICE Guidewire	Intermediate, 182 cm	182	Straight	5 Pack
H7491213301J2	ChoICE Guidewire	Intermediate, 182 cm	182	J-Tip	5 Pack
H74912117011	ChoICE Guidewire	Intermediate, 300 cm	300	Straight	Single Pack
H7491211701J1	ChoICE Guidewire	Intermediate, 300 cm	300	J-Tip	Single Pack
H74912117012	ChoICE Guidewire	Intermediate, 300 cm	300	Straight	5 Pack
H7491211701J2	ChoICE Guidewire	Intermediate, 300 cm	300	J-Tip	5 Pack
H74912134011	ChoICE Guidewire	Standard, 182 cm	182	Straight	Single Pack
H7491213401J1	ChoICE Guidewire	Standard, 182 cm	182	J-Tip	Single Pack
H74912134012	ChoICE Guidewire	Standard, 182 cm	182	Straight	5 Pack
H7491213401J2	ChoICE Guidewire	Standard, 182 cm	182	J-Tip	5 Pack
H74912118011	ChoICE Guidewire	Standard, 300 cm	300	Straight	Single Pack
H7491211801J1	ChoICE Guidewire	Standard, 300 cm	300	J-Tip	Single Pack
H74912118012	ChoICE Guidewire	Standard, 300 cm	300	Straight	5 Pack
H7491211801J2	ChoICE Guidewire	Standard, 300 cm	300	J-Tip	5 Pack
H74912130010	Luge Guidewire	Moderate Support, 182 cm	182	Straight	Single Pack
H7491213001J0	Luge Guidewire	Moderate Support, 182 cm	182	J-Tip	Single Pack

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Page 3 of 14

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Catalogue Number	Device Name	Rail Support	Length (cm)	Tip Configuration	Package Configuration
H74912130012	Luge Guidewire	Moderate Support, 182 cm	182	Straight	5 pack
H7491213001J2	Luge Guidewire	Moderate Support, 182 cm	182	J-Tip	5 Pack
H74912100010	Luge Guidewire	Moderate Support, 300 cm	300	Straight	Single Pack
H7491210001J0	Luge Guidewire	Moderate Support, 300 cm	300	J-Tip	Single Pack
H74912100012	Luge Guidewire	Moderate Support, 300 cm	300	Straight	5 Pack
H7491210001J2	Luge Guidewire	Moderate Support, 300 cm	300	J-Tip	5 Pack
H74912136011	Mailman Guidewire	Super Support, 182 cm	182	Straight	Single Pack
H7491213601J1	Mailman Guidewire	Super Support, 182 cm	182	J-Tip	Single Pack
H74912136012	Mailman Guidewire	Super Support, 182 cm	182	Straight	5 Pack
H7491213601J2	Mailman Guidewire	Super Support, 182 cm	182	J-Tip	5 Pack
H74912120011	Mailman Guidewire	Super Support, 300 cm	300	Straight	Single Pack
H7491212001J1	Mailman Guidewire	Super Support, 300 cm	300	J-Tip	Single Pack
H74912120012	Mailman Guidewire	Super Support, 300 cm	300	Straight	5 Pack
H7491212001J2	Mailman Guidewire	Super Support, 300 cm	300	J-Tip	5 Pack

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Page 4 of 14

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Catalogue Number	Device Name	Rail Support	Length (cm)	Tip Configuration	Package Configuration
H74912160011	ChoICE PT Guidewire	Floppy, 182 cm	182	Straight	Single Pack
H7491216001J1	ChoICE PT Guidewire	Floppy, 182 cm	182	J-Tip	Single Pack
H74912160012	ChoICE PT Guidewire	Floppy, 182 cm	182	Straight	5 Pack
H7491216001J2	ChoICE PT Guidewire	Floppy, 182 cm	182	J-Tip	5 pack
H74912154011	ChoICE PT Guidewire	Floppy, 300 cm	300	Straight	Single Pack
H7491215401J1	ChoICE PT Guidewire	Floppy, 300 cm	300	J-Tip	Single Pack
H74912154012	ChoICE PT Guidewire	Floppy, 300 cm	300	Straight	5 Pack
H7491215401J2	ChoICE PT Guidewire	Floppy, 300 cm	300	J-Tip	5 Pack
H74912161011	ChoICE PT Guidewire	Extra Support, 182 cm	182	Straight	Single Pack
H7491216101J1	ChoICE PT Guidewire	Extra Support, 182 cm	182	J-Tip	Single Pack
H74912161012	ChoICE PT Guidewire	Extra Support, 182 cm	182	Straight	5 Pack
H7491216101J2	ChoICE PT Guidewire	Extra Support, 182 cm	182	J-Tip	5 Pack
H74912155011	ChoICE PT Guidewire	Extra Support, 300 cm	300	Straight	Single Pack
H7491215501J1	ChoICE PT Guidewire	Extra Support, 300 cm	300	J-Tip	Single Pack
H74912155012	ChoICE PT Guidewire	Extra Support, 300 cm	300	Straight	5 Pack
H7491215501J2	ChoICE PT Guidewire	Extra Support, 300 cm	300	J-Tip	5 Pack

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Page 5 of 14

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Catalogue Number	Device Name	Rail Support	Length (cm)	Tip Configuration	Package Configuration
H74914902011	PT Graphix Guidewire	Intermediate, 182 cm	182	Straight	Single Pack
H7491490201J1	PT Graphix Guidewire	Intermediate, 182 cm	182	J-Tip	Single Pack
H74914902012	PT Graphix Guidewire	Intermediate, 182 cm	182	Straight	5 Pack
H7491490201J2	PT Graphix Guidewire	Intermediate, 182 cm	182	J-Tip	5 Pack
H74914914011	PT Graphix Guidewire	Intermediate, 300 cm	300	Straight	Single Pack
H7491491401J1	PT Graphix Guidewire	Intermediate, 300 cm	300	J-Tip	Single Pack
H74914914012	PT Graphix Guidewire	Intermediate, 300 cm	300	Straight	5 Pack
H7491491401J2	PT Graphix Guidewire	Intermediate, 300 cm	300	J-Tip	5 Pack
H74914905011	PT Graphix Guidewire	Super Support, 182 cm	182	Straight	Single Pack
H7491490501J1	PT Graphix Guidewire	Super Support, 182 cm	182	J-Tip	Single Pack
H74914905012	PT Graphix Guidewire	Super Support, 182 cm	182	Straight	5 Pack
H7491490501J2	PT Graphix Guidewire	Super Support, 182 cm	182	J-Tip	5 Pack
H74914903011	PT Graphix Guidewire	Standard, 182 cm	182	Straight	Single Pack
H7491490301J1	PT Graphix Guidewire	Standard, 182 cm	182	J-Tip	Single Pack
H74914903012	PT Graphix Guidewire	Standard, 182 cm	182	Straight	5 Pack

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Page 6 of 14

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Catalogue Number	Device Name	Rail Support	Length (cm)	Tip Configuration	Package Configuration
H7491490301J2	PT Graphix Guidewire	Standard, 182 cm	182	J-Tip	5 Pack
H7491213201M2	ChoICE Magnet Guidewire	Floppy, 182 cm	182	Straight	5 Pack
H7491213201MJ2	ChoICE Magnet Guidewire	Floppy, 182 cm	182	J-Tip	5 Pack
H7491213501M2	ChoICE Magnet Guidewire	Extra Support, 182 cm	182	Straight	5 Pack
H7491213501MJ2	ChoICE Magnet Guidewire	Extra Support, 182 cm	182	J-Tip	5 Pack
H7491213301M2	ChoICE Magnet Guidewire	Intermediate, 182 cm	182	Straight	5 Pack
H7491213301MJ2	ChoICE Magnet Guidewire	Intermediate, 182 cm	182	J-Tip	5 Pack
H7491213401M2	ChoICE Magnet Guidewire	Standard, 182 cm	182	Straight	5 Pack
H7491213401MJ2	ChoICE Magnet Guidewire	Standard, 182 cm	182	J-Tip	5 Pack
H7491213001M2	Luge Magnet Guidewire	Moderate Support, 182 cm	182	Straight	5 Pack
H7491213001MJ2	Luge Magnet Guidewire	Moderate Support, 182 cm	182	J-Tip	5 Pack
H7491213601M2	Mailman Magnet Guidewire	Super Support, 182 cm	182	Straight	5 Pack
H7491213601MJ2	Mailman Magnet Guidewire	Super Support, 182 cm	182	J-Tip	5 Pack

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Page 7 of 14

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Catalogue Number	Device Name	Rail Support	Length (cm)	Tip Configuration	Package Configuration
H7491216001M2	ChoICE PT Magnet Guidewire	Floppy, 182 cm	182	Straight	5 Pack
H7491216001MJ2	ChoICE PT Magnet Guidewire	Floppy, 182 cm	182	J-Tip	5 Pack
H7491216101M2	ChoICE PT Magnet Guidewire	Extra Support, 182 cm	182	Straight	5 Pack
H7491216101MJ2	ChoICE PT Magnet Guidewire	Extra Support, 182 cm	182	J-Tip	5 Pack
H7491490201M2	PT Graphix Magnet Guidewire	Intermediate, 182 cm	182	Straight	5 Pack
H7491490201MJ2	PT Graphix Magnet Guidewire	Intermediate, 182 cm	182	J-Tip	5 Pack
H7491490501M2	PT Graphix Magnet Guidewire	Super Support, 182 cm	182	Straight	5 Pack
H7491490501MJ2	PT Graphix Magnet Guidewire	Super Support, 182 cm	182	J-Tip	5 Pack
H7491490301M2	PT Graphix Magnet Guidewire	Standard, 182 cm	182	Straight	5 Pack
H7491490301MJ2	PT Graphix Magnet Guidewire	Standard, 182 cm	182	J-Tip	5 Pack

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Page 8 of 14

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Issued To:

Boston Scientific Corporation
300 Boston Scientific Way
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01752
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Product: Left Ventricular Lead Guidewires

Classification: Class III

Intended Purpose per IFU: Boston Scientific ACUITY Strait-Trak and ACUITY Mailman Venous Guide wires are intended to facilitate the placement of Boston Scientific or Guidant Left Ventricular (LV) leads within the Coronary Sinus (CS) vasculature

Catalogue (Model) Number	Device Name	Rail Support	Length (cm)	Tip Configuration	Package Configuration
90460000-01 (7082)	ACUITY Strait-Trak Guidewire	Extra Support	182	Straight	1 Pack
90460000-02 (7082)	ACUITY Strait-Trak Guidewire	Extra Support	182	Straight	1 Pack
90460000-03 (7082)	ACUITY Strait-Trak Guidewire	Extra Support	182	Straight	1 Pack
90460000-04 (7082)	ACUITY Strait-Trak Guidewire	Extra Support	182	Straight	1 Pack
90460000-05 (7082)	ACUITY Strait-Trak Guidewire	Extra Support	182	Straight	1 Pack
90459993-01 (7081)	ACUITY Mailman Guidewire	Super Support	182	Straight	1 Pack
90459993-02 (7081)	ACUITY Mailman Guidewire	Super Support	182	Straight	1 Pack
90459993-03 (7081)	ACUITY Mailman Guidewire	Super Support	182	Straight	1 Pack
90459993-04 (7081)	ACUITY Mailman Guidewire	Super Support	182	Straight	1 Pack

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Page 9 of 14

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Issued To:

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough
Massachusetts
01752
USA

Product: Left Ventricular Lead Guidewires

Classification: Class III

Intended Purpose per IFU: Boston Scientific ACUTY Whisper View Guide Wires with Hydrophilic Coating are intended to facilitate the placement of Boston Scientific or Guidant Left Ventricular (LV) leads within the Coronary Venous vasculature.

Catalogue (Model) Number	Device Name	Rail Support	Length (cm)	Tip Configuration	Package Configuration
90724668-02 (4640)	ACUTY Whisper View Guidewire	Extra Support	190	Straight	5 Pack
90724668-03 (4640)	ACUTY Whisper View Guidewire	Extra Support	190	Straight	5 Pack
90724668-04 (4640)	ACUTY Whisper View Guidewire	Extra Support	190	Straight	5 Pack
90724668-05 (4640)	ACUTY Whisper View Guidewire	Extra Support	190	Straight	5 Pack
90724668-07 (4641)	ACUTY Whisper View Guidewire	Extra Support	190	J-Tip	5 Pack
90724668-08 (4641)	ACUTY Whisper View Guidewire	Extra Support	190	J-Tip	5 Pack
90724668-09 (4641)	ACUTY Whisper View Guidewire	Extra Support	190	J-Tip	5 Pack
90724668-10 (4641)	ACUTY Whisper View Guidewire	Extra Support	190	J-Tip	5 Pack
90724668-12 (4642)	ACUTY Whisper View Guidewire	Extra Support	190	Straight	5 Pack

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Page 10 of 14

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Catalogue (Model) Number	Device Name	Rail Support	Length (cm)	Tip Configuration	Package Configuration
90724668-13 (4642)	ACUITY Whisper View Guidewire	Distal Support	190	Straight	5 Pack
90724668-14 (4642)	ACUITY Whisper View Guidewire	Distal Support	190	Straight	5 Pack
90724668-15 (4642)	ACUITY Whisper View Guidewire	Distal Support	190	Straight	5 Pack
90724668-17 (4643)	ACUITY Whisper View Guidewire	Distal Support	190	J-Tip	5 Pack
90724668-18 (4643)	ACUITY Whisper View Guidewire	Distal Support	190	J-Tip	5 Pack
90724668-19 (4643)	ACUITY Whisper View Guidewire	Distal Support	190	J-Tip	5 Pack
90724668-20 (4643)	ACUITY Whisper View Guidewire	Distal Support	190	J-Tip	5 Pack
90724668-22 (4647)	ACUITY Whisper View Guidewire	Extra Distal Support	190	Straight	5 Pack
90724668-23 (4647)	ACUITY Whisper View Guidewire	Extra Distal Support	190	Straight	5 Pack

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Page 11 of 14

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Catalogue (Model) Number	Device Name	Rail Support	Length (cm)	Tip Configuration	Package Configuration
90724668-24 (4647)	ACUITY Whisper View Guidewire	Extra Distal Support	190	Straight	5 Pack
90724668-25 (4647)	ACUITY Whisper View Guidewire	Extra Distal Support	190	Straight	5 Pack
90724668-27 (4648)	ACUITY Whisper View Guidewire	Extra Distal Support	190	J-Tip	5 Pack
90724668-28 (4648)	ACUITY Whisper View Guidewire	Extra Distal Support	190	J-Tip	5 Pack
90724668-29 (4648)	ACUITY Whisper View Guidewire	Extra Distal Support	190	J-Tip	5 Pack
90724668-30 (4648)	ACUITY Whisper View Guidewire	Extra Distal Support	190	J-Tip	5 Pack

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Page 12 of 14

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Certificate History

Date	Reference Number	Action
30 June 2014	10149518	First Issue. Mirror certificate to CE 555158.
15 October 2014	10152078	Addition of Synergy Health in Costa Rica as a qualified sterilization facility for the BSC 2000-2 cycle.
29 January 2015	10153744	Certificate renewal.
23 April 2015	10154401	Design change to the proximal end of the Choice, Choice PT, ChoicePT Graphix, Mailman, and Luge Guide Wires to create the "AddWire" version under the current catalogue numbers. Name change for the existing devices to become the "Magnet" version and creation of new catalogue codes for these devices.
10 November 2015	10154829	DuPont Tyvek Medical Transition Project update.
07 February 2018	8727903	Sterilization optimization changes: Synergy Health Chamber 3 Costa Rica, Chamber 8 and 9 Tullamore, Chamber 1, 2, 3, 5, 6, 7, 8, 9 and 10 Coventry.

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Date	Reference Number	Action
16 November 2018	9635221	Introduction of the optimized BSC2000-2 EO sterilization cycle into chamber 4 at the Steris Costa Rica Facility.
05 March 2019	8250540	Traceable to NB 0086.
20 November 2019	9733049	Qualification of Palladium-Iridium as an alternate to Platinum-Tungsten as the distal spring coil material for the Choice, Mailman, and Luge guidewires
24 January 2020	3103157	Certificate renewal and addition of product device table.
02 March 2020	3081357	Change to reduce the EO concentration in the BSC2000-2 EO cycle. Administrative update to product table formatting.
Current	3284130	Addition of Boston Scientific Limited, Galway, Ireland, as a qualified EO sterilization facility for the BSC2000-2 cycle into chamber 1 and 2.

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Page 14 of 14

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.
 This certificate was issued electronically and is bound by the conditions of the contract.

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