



By Royal Charter

EC Design-Examination Certificate

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

No.

CE 616368

Issued To:

**Boston Scientific Corporation
300 Boston Scientific Way
Marlborough
Massachusetts
01752
USA**

In respect of:

Amplatz Super Stiff Guidewires

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 5

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, 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.
A member of BSI Group of Companies.

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Supplementary Information to CE 616368

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
M001465001	Amplatz Super Stiff, Box 5	J-Tip, OD .035 in, Length 145 cm	The Amplatz Super Stiff guidewire facilitates catheter placement and exchange during diagnostic or interventional procedures. Not intended for use in coronary arteries.	Class III
M001465011		J-Tip, OD .035 in, Length 180 cm		
M001465021		J-Tip, OD .035 in, Length 260 cm		
M001465031		J-Tip, OD .038 in, Length 145 cm		
M001465041		J-Tip, OD .038 in, Length 180 cm		
M001465091		S-Tip, OD .035 in, Length 260 cm		
M001465101		S-Tip, OD .038 in, Length 260 cm		
M001465171		S-Tip, OD .038 in, Length 145 cm		
M001465181		S-Tip, OD .038 in, Length 145 cm		

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
M001465191	Amplatz Super Stiff, Box 5	S-Tip, OD .038 in, Length 180 cm	The Amplatz Super Stiff guidewire facilitates catheter placement and exchange during diagnostic or interventional procedures. Not intended for use in coronary arteries.	Class III
M001465201		S-Tip, OD .038 in, Length 260 cm		
M001465231		S-Tip, OD .035 in, Length 145 cm		
M001465241		S-Tip, OD .035 in, Length 145 cm		
M001465251		S-Tip, OD .035 in, Length 180 cm		
M001465261		S-Tip, OD .035 in, Length 260 cm		
M001465631		S-Tip, OD .035 in, Length 75 cm		
M001465641		S-Tip, OD .038 in, Length 75 cm		

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
H7493922311	Amplatz Super Stiff, Box 5	S-Tip, OD .035 in, Length 300 cm	The Amplatz Super Stiff guidewire facilitates catheter placement and exchange during diagnostic or interventional procedures. Not intended for use in coronary arteries.	Class III
H7493922321		S-Tip, OD .035 in, Length 300 cm		

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Certificate History

Date	Reference Number	Action
30 June 2014	10149518	First Issue. Mirror certificate to CE 582135.
15 October 2014	10152078	Addition of Synergy Health in Costa Rica as a qualified sterilization facility for the BSC 2000-2 cycle.
10 November 2015	10158429	DuPont Tyvek Medical Transition Project Update.
17 January 2017	10168325	Certificate Renewal.
25 April 2017	10159940	Retrospective review of a packaging change reducing the number of configurations across the product families.
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.
16 November 2018	9635221	Introduction of the optimized BSC-2000-2 EO sterilization cycle into chamber 4 at the Steris Costa Rica Facility.
05 March 2019	8250540	Traceable to NB 0086.
02 March 2020	3081357	Change to reduce the EO concentration in the BSC2000-2 EO cycle.
19 June 2020	3125201	Certificate Renewal. Update to supplementary information table.
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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