

**Boston Scientific Corporation's  
2020 Compliance Declaration to BSC's California Comprehensive Compliance Program**

Based on an assessment as of June 30, 2020, to our knowledge, Boston Scientific Corporation, in all material respects, is in compliance with Boston Scientific Corporation's California Comprehensive Compliance Program (see attached) as well as the requirements of California Health and Safety Code, Division 104, Part 15, Chapter 8, Sections 119400-119402 (the "Statute"), as in effect on June 30, 2020, based on our good faith understanding of the requirements of the Statute as it may apply to medical device manufacturers. In conjunction with this declaration please note that, from time to time, through audits, our disclosure program, or otherwise, Boston Scientific Corporation may identify potential or actual violations of provisions of our compliance program, including the California Comprehensive Compliance Program and the annual limit on gifts to individual medical or health care professionals. In those instances, Boston Scientific Corporation promptly investigates and responds appropriately to any violations consistent with our policies addressing noncompliance or misconduct, as described in the California Comprehensive Compliance Program.

This declaration covers all of the members of the Boston Scientific family of companies.

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## **Boston Scientific Corporation's California Comprehensive Compliance Program**

As part of our ongoing efforts in the area of legal and ethical compliance, Boston Scientific has developed this California Comprehensive Compliance Program (“California Program”) pursuant to California Health and Safety Code, Division 104, Part 15, Chapter 8, Sections 119400-119402 (the “Statute”). Our California Program sets forth certain of our policies regarding relationships with California “medical or health professionals” as defined in the Statute. This is a summary document and does not include all of the numerous policies and practices that comprise our California Program. Our California Program is dynamic and evolves as the laws and regulations that impact our industry evolve. Accordingly, the California Program is subject to change.

The U.S. Department of Health and Human Services’ April 2003 publication “OIG Compliance Program Guidance for Pharmaceutical Manufacturers” (the “OIG Guidance”) referenced in the Statute applies to the pharmaceutical industry. However, a footnote in the OIG Guidance states that the compliance program elements and potential risk areas may also have application to manufacturers in other industries, with a specific reference to the medical device industry. The OIG Guidance also notes that measures adopted by a pharmaceutical manufacturer should be tailored to fit the unique environment of the company. Consistent with the OIG Guidance, we have tailored our California Program to the nature of our business as a medical device manufacturer and to fit our unique environment. In this regard, we, as a medical device company, have adopted policies (our *U.S. Customer Financial Relationship Policies*) that implement the Code of Ethics on Interactions with Health Care Professionals adopted by the Advanced Medical Technology Association (the “AdvaMed Code”). The AdvaMed Code is consistent in many aspects with the Pharmaceutical Research and Manufacturers of America’s “Code on Interactions with Health Care Professionals” (the “PhRMA Code”) to which the Statute makes reference.

Our California Program is integrated with our company-wide compliance program, which includes the following:

(1) *Written Code of Conduct.* Our Code of Conduct is distributed to all workers (employees and non-employees who perform work regularly at a Boston Scientific location) upon commencement of their working relationship and whenever changes are made to the Code. Our Code is available in multiple languages on the Compliance & Ethics page of <http://www.bostonscientific.com>. Policies implementing topics covered in our Code are distributed to workers for whom the policy is relevant and also posted on internal websites.

(2) *Compliance Officer.* Our compliance officer is responsible for developing, operating, and monitoring the compliance program. This individual is a Vice President who reports regularly to a Committee of our Board of Directors on matters relating to compliance (at least quarterly). Our compliance officer also oversees the governance of our compliance program which includes a network of compliance committees, which generally help to ensure that the compliance program is reasonably designed, implemented, and enforced so that the program is effective in preventing and detecting unlawful conduct and reinforces a corporate culture that encourages ethical conduct and a commitment to compliance with the law.

(3) *Training Program.* All of our U.S. sales and marketing employees, as well as other U.S. employees who regularly interact with U.S. health care professionals, are required to timely complete a Fraud and Abuse Prevention training course through our electronic training systems. We also offer periodic in-person training on topics included in the *U.S. Customer Financial Relationship Policies*. Employee training and education programs increase awareness of the legal and ethical implications of abiding by our Code of Conduct and related policies, and making sound and ethical business decisions.

(4) *Communications and Complaint Reporting.* Boston Scientific is committed to fostering effective lines of communication between management and employees. We have adopted confidentiality and non-retribution/non-retaliation policies. Compliance questions or reports of potential violations may also be directed to a toll-free phone line and/or web address, available globally, that can handle calls and/or reports in multiple languages, and which allows for anonymous reporting and two-way communication with compliance program personnel.

(5) *Periodic Audits.* Boston Scientific's compliance program includes ongoing efforts to monitor, audit and assess compliance with the Code of Conduct and related policies, including the California Program.

(6) *Policies related to Noncompliance or Misconduct.* Boston Scientific responds promptly and impartially to questions, concerns, and reports of wrongdoing. We have implemented processes for the prompt investigation of potential violations of our compliance program, including the California Program, and development of an appropriate response to violations, such as the initiation of appropriate corrective action designed to mitigate the risk of violations recurring while maintaining a response that is consistent with the level and frequency of the violation, which can include reporting instances of noncompliance to law enforcement authorities in appropriate circumstances. We maintain a database of situations that are investigated to facilitate consistency in the company's response and corrective/preventive action in similar circumstances. Our Code of Conduct specifically prohibits retaliation against an individual arising from a good-faith report of a Code of Conduct, company policy, or integrity concern, and investigations are handled as confidentially as possible.

(7) *Maximum Annual Dollar Limit.* The Statute requires that we establish a specific maximum annual dollar limit on gifts, promotional materials, or items or activities that we may give or otherwise provide to an individual California medical or health care professional. Our annual (July 1 to June 30), per individual, limit on gifts, promotional materials, or items or activities that we may give or otherwise provide to an individual California medical or health care professional is \$2,000, and all such items provided are required to be consistent with our *U.S. Customer Financial Relationship Policies*. As of July 1, 2009, our policies prohibit the provision of gifts, entertainment and/or recreational activities to any U.S. health care professional. Most California medical or health care professionals receive much less than \$2,000 worth of educational items, product literature and related items from us. However, we have established \$2,000 as our maximum amount because, as a global company, on occasion several of our different business units and departments may interact with the same medical or health professional, any of which may provide small educational items and product literature and related items to an individual California medical or health professional, which amounts must be aggregated for purposes of the Statute. Consistent

with the Statute, this dollar limit does not include (a) product samples of our medical devices intended for free distribution to patients that are provided to hospitals and other medical institutions (or on rare occasions, to a California medical or health care professional), (b) financial support for continuing medical education forums, (c) financial support for health educational scholarships, or (d) payments made for legitimate professional services provided by a California medical or health care professional. Consistent with the AdvaMed Code, this dollar limit also does not include plant visits to observe our quality production facilities, training on the safe and effective uses of our medical devices consistent with approved uses, which for many products is required by the U.S. Food and Drug Administration and/or to help health care providers provide better patient care, grants made to support research, fellowship programs and/or charitable initiatives of a California medical or health professional.

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