

California Compliance Declaration

POLICY

The following applies to our Compliance Program in California.

We have always held ourselves to the highest ethical standards of business conduct. It is imperative that we comply with the many laws and regulations that affect our activities worldwide and that we act in accordance with the company's values, including demanding honesty and ethical behavior in all that we do. As part of our overall continuing efforts in compliance, we have a Comprehensive Compliance Program that is reasonably designed to prevent and detect violations.

PROCEDURE

1. Distinction of Device Manufacturers

The AdvaMed Code of Ethics on Interactions with Healthcare Professionals recognizes that the medical device industry is significantly different than the pharmaceutical industry. Consistent with the HHS-OIG guidance, we have tailored our Comprehensive Compliance Program to the nature of our business as a medical device manufacturer.

While the California law makes references to compliance with the PhRMA Code on Interactions with Healthcare Professionals, we manufacture medical devices rather than pharmaceutical products, and have therefore adopted the AdvaMed Code and designed policies and procedures for compliance, which are substantially similar to the PhRMA Code. Thus, while we have formally adopted the AdvaMed Code, we believe that adherence to the AdvaMed Code also constitutes compliance with the PhRMA Code for purposes of satisfying the requirements of the California law.

2. Description of Compliance

To the best of our knowledge and belief, based on our good faith understanding of the statutory requirements, we have established a Comprehensive Compliance Program compliant with requirements of California Health and Safety Code §§ 119400-119402.

We have developed this Comprehensive Compliance Program tailored to the size, organizational structure, and resources of the company, and implemented to meet the compliance goals set forth by the State of California. The description of our Comprehensive Compliance Program reflects the plan we have implemented to comply with California law.

To our knowledge and belief, we are in material respects, in compliance with our Comprehensive Compliance Program as described, meaning that we have established the elements outlined, and where procedures are described, we have set up programs to initiate these procedures.

3. Changes to Comprehensive Compliance Program

Compliance is a dynamic concept that must be adapted to the characteristics of particular businesses and changes to the legal environment. We therefore continue to review and revise the Comprehensive Compliance Program to improve it, and it is possible (and likely) that we will do so and possibly make changes to the Comprehensive Compliance Program from time to time.



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4. Qualifiers

Please recognize, as government standards on compliance programs, including the U.S. Sentencing Guidelines and the HHS-OIG Guidance, recognize, that no program can completely prevent individual employees from improper conduct.

While we are not making a representation that every employee will always fully comply and while we cannot completely eliminate the possibility that an employee will violate these standards, the purpose of our Comprehensive Compliance Program is to help identify and deter potential violations and discipline employees as necessary.

We believe that our Comprehensive Compliance Program is reasonably designed to prevent and detect violations.

5. Timeframe Covered

This declaration was made May 2023. As noted above, it is possible and likely that we will update our Comprehensive Compliance Program on an ongoing basis.