



## **BlueWind Medical - California Compliance Declaration – August 2022**

The following declaration applies to the company's compliance program in California:

We have always held ourselves to the highest 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 policies, procedures, and values, including expecting accountability, responsibility, honesty and ethical behavior in all that we do. As part of our overall continuing efforts in compliance, we have developed a Comprehensive Compliance Program that is reasonably designed to prevent and detect violations.

### **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 refers 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 for compliance, which is 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.

### **Description of Compliance**

To the best of our knowledge and belief and 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 developed and implemented our program and tailored it to the size, organizational structure, and resources of BlueWind Medical to meet the compliance goals set forth by the State of California. The description of our Comprehensive Compliance Program, provided on our website, reflects the plan we have implemented to comply with California law. To our knowledge and belief, we are, in all material respects, in compliance with our Comprehensive Compliance Program.

## **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 the Comprehensive Compliance Program to enhance 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.

### **Qualifiers**

Please recognize, as government standards on compliance programs, including the U.S. Sentencing Guidelines and HHS-OIG Guidance, we 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 eliminate the possibility that an employee may violate these standards, the purpose of our Comprehensive Compliance Program is to help educate and guide employees, as well as identify and deter potential violations, and discipline employees as or if necessary.