



## Comprehensive Compliance Program

---

### **PURPOSE**

The fundamental elements of BlueWind Medical’s Comprehensive Compliance Program (“the Program”) are described below. 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. Note that the Program is constantly evolving to meet the changing needs and demands of the global compliance environment and of BlueWind Medical. We continuously review and enhance the Program and reserve the right to continue to do so at any time in the future without notice.

---

### **COMPLIANCE PROGRAM**

BlueWind Medical conducts its business in compliance with all applicable global guidelines, laws, and regulations, as well as applicable industry guidelines that govern the medical device industry.

It is illegal to provide, offer, or agree to provide or offer, or accept, obtain, or agree to accept or attempt to obtain, a kickback or bribe. A kickback or bribe may be defined as any money, fee, payment, commission, credit, gift, gratuity, transfer of value, or compensation of any kind that is provided directly or indirectly, and that has as one of its purposes the improper obtaining or rewarding of favorable treatment in a business transaction. BlueWind Medical’s position on kickbacks and bribes is clear – they are illegal and are not allowed.

An individual who is unsure whether a violation of any law, regulation or policy occurred must seek advice from their manager or the Vice President of Compliance. Complaints or reports of alleged violations of law should be made via the company’s Communication Channels (Open Door Reporting or Helpline) to any member of senior Leadership, Vice President of Compliance, or Human Resources. They may be made anonymously if desired. Anonymity will be maintained during any fact finding or investigation to the extent practicable and/or possible.

It is not sufficient simply to take note of the Program. Every individual is responsible and accountable for implementation, and is called upon to review his or her own behavior in light of the Program and to determine where enhancements may be possible.

Employees should be aware of global laws and regulations regarding interactions with Healthcare Professionals, for example, the Federal Anti-Kickback Statute (AKS), and the constraints it places on the marketing and promotion of products reimbursable by any Federal health care programs. The AKS is a criminal prohibition against payments (in any form, whether the payments are direct or indirect) made in whole or in part to induce or reward referrals of Federal health care business. The AKS potentially implicates not only the offer or payment of anything of value for patient or business referrals, but also the offer or payment of anything of value in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or ordering of any item or service reimbursable in whole or part by a federal health care program. Violations of the AKS can result in criminal sanctions, exclusion/debarment from government programs and/or civil fines to both the individual or entity that authorizes, offers or pays a kickback, and the individual or entity that solicits or receives the kickback.



## Comprehensive Compliance Program

---

### **FUNDAMENTAL GUIDELINES OF THE PROGRAM**

BlueWind Medical strives to obey the laws and regulations that govern its business. All individuals must respect and obey all laws, rules and regulations that apply to our business. All individuals should understand the laws and regulations which apply to them in the performance of their duties and ensure that BlueWind Medical complies with the laws, rules and regulations, as well as the codes and policies that govern how the company conducts business. Without reservation, BlueWind Medical adopts and advocates the AdvaMed Code of Ethics on Interactions with Healthcare Professionals, which facilitates our company's ethical interactions with Health Care Professionals in the United States, and the European MedTech Code of Ethical Conduct which is intended to provide guidance as to the minimum standards which apply to our business practices in Europe and, generally, elsewhere.

### **LEADERSHIP – VICE PRESIDENT OF COMPLIANCE**

BlueWind Medical has designated a Vice President of Compliance to implement and manage the Compliance Program, which includes policies, procedures, training, monitoring, conducting investigations, and establishing best practices and preventative measures. The Compliance policies contain the procedures that BlueWind Medical has adopted to demonstrate the company's commitment to ethical, honest and responsible conduct when interacting with Health Care Professionals.

### **WRITTEN STANDARDS – COMPLIANCE POLICIES AND PROCEDURES**

BlueWind Medical maintains Compliance policies which every individual will follow when conducting business transactions. The policies and procedures include guidelines for ethical standards and compliance with applicable laws which are critical to the company's ability to collaborate with Health Care Professionals.

### **EFFECTIVE LINES OF COMMUNICATION**

BlueWind Medical encourages open and direct communication and discussion regarding any requests for guidance or clarity, and/or compliance concerns. The company provides a number of resources (Communication Channels) employees can use to ask a question, obtain guidance, or report a compliance concern. Resources for reporting concerns include talking with their manager, the Vice President of Compliance, Human Resources, any member of senior leadership, or utilizing the company's Helpline, an independent, third-party toll-free telephone number or Web portal that anyone can access 24 hours a day, 7 days a week. BlueWind Medical does not tolerate any form of retaliation against an individual arising from a good-faith report of a potential violation of the Program, a related policy, or of an ethical or business concern.

### **TRAINING AND EDUCATION**

Employees will undergo compliance training on the laws and industry guidelines regarding business transactions with Health Care Professionals.

### **ACCOUNTABILITY**

BlueWind Medical supports ethical and compliant behavior and requires every individual to adhere to the policies in the Program as a condition of their employment.



## Comprehensive Compliance Program

---

### **ASSESSMENT - AUDITING AND MONITORING, ENFORCEMENT OF PROGRAM**

BlueWind Medical will self-assess and monitor its compliance with policies and procedures. The Vice President of Compliance will conduct a periodic internal audit of the company regarding interactions with and/or payments to Health Care Professionals. If it is determined that a compliance violation has occurred, reasonable steps will be taken to respond appropriately to the violation, prevent the occurrence of future violations of a similar nature, and support preventative measures and corrective actions.

### **REMEDIATION - INVESTIGATING AND MANAGING ALLEGED AND CONFIRMED INSTANCES OF NON-COMPLIANCE AND DISCIPLINARY STANDARDS**

BlueWind Medical has established a framework of standards of conduct for individuals relating to internal fact finding/investigations and managing alleged and confirmed instances of non-compliance. Although each situation is considered on a case-by-case basis, the company consistently undertakes appropriate corrective action to address perceived or actual inappropriate conduct and to deter future violations.

### **TIMEFRAME COVERED**

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