

# Comprehensive Compliance Program and Declaration

## INTRODUCTION

EdgeEndo® (or the “Company”) is committed to high standards of ethical conduct and corporate compliance. To that end, we have established a Comprehensive Compliance Program designed to incorporate key elements set-out in the Compliance Program Guidance for Pharmaceuticals issued by the U.S. Department of Health and Human Services Office of Inspector General (OIG). The OIG’s Compliance Program Guidance provides relevant information for healthcare company compliance programs.

The purpose of EdgeEndo®’s Comprehensive Compliance Program is to prevent, detect and remediate violations of Company standards and applicable law. We describe below the fundamental elements of the Company’s Comprehensive Compliance Program, which has been tailored to fit EdgeEndo®’s size and resources, as well as the unique interactions that the Company has as a manufacturer and distributor of dental and medical products. As envisioned by OIG’s Compliance Program Guidance, the Company endeavors to continually improve its Comprehensive Compliance Program in response to ever evolving business activities, applicable laws, and associated compliance risks.

## COMPREHENSIVE COMPLIANCE PROGRAM

### Written Policies and Standards

We have adopted written policies and standards that provide guidance to our employees in their dealings with health care professionals, customers, suppliers, government entities, society at large, other employees, and other third parties. They also address the methods and means by which the Comprehensive Compliance Program is administered and enforced.

The cornerstone of our written standards is EdgeEndo®’s Worldwide Business Standards, which is supplemented by policies and procedures, guidelines, directives and other communications that address applicable federal, state and foreign laws and industry standards relating to the marketing, promotion, distribution and sale of the Company’s products and services. EdgeEndo® has also adopted a Marketing Code of Conduct Policy governing interactions with healthcare professionals.

In addition, in accordance with California law, EdgeEndo® has set an annual dollar limit on items or activities of value (defined in the law) that the Company provides to each individual California health professional (\$2500 per covered recipient per year).



## **Leadership and Oversight**

The Company's Chief Executive Officer has appointed a Chief Ethics and Compliance Officer ("CECO") who has overall responsibility for managing and overseeing the Compliance Program, is empowered with appropriate authority to exercise independent judgment, and has free and unencumbered access to senior management and the Board of Directors.

In order to assist the CECO in implementing, executing and monitoring the Comprehensive Compliance Program, the Company's Chief Executive Officer has also appointed a Compliance Committee comprised of members of senior management. This Committee assists the CECO, as needed, in implementing the Compliance Program.

The Compliance Committee and/or CECO periodically report to the Board of Directors (or a committee thereof) concerning the Comprehensive Compliance Program. Training and Education EdgeEndo® is committed to effectively communicating our standards and procedures to Company personnel. Our training activities include a combination of in-person presentations, online web modules, printed materials, and individualized sessions. EdgeEndo® periodically reviews and updates its training programs and identifies additional areas of training on an "as needed" basis.

## **Communication and Helpline Reporting**

EdgeEndo® encourages open and candid discussion between management and employees regarding any compliance concerns. Our goal is that all employees when seeking answers to questions or reporting potential instances of misconduct, should know to whom to turn for a meaningful response and should be able to do so without fear of retaliation. Employees are encouraged to report their concerns to a) their manager, b) the Compliance Helpline, c) the Ethics & Compliance Department, d) any member of the Compliance Committee; (e) the General Counsel's office or local Legal department if outside the U.S., (f) Internal Audit, (g) their local Human Resources contact, or (h) other senior Company official. EdgeEndo® maintains a Compliance Helpline through a third-party vendor with a toll-free number (by country) and web portal to receive reports from employees and others in connection with alleged violations of our standards or applicable laws by any employee, contractor, subcontractor, supplier, customer, or other person. Reports to the Compliance Helpline may be made anonymously, if desired.

## **Risk Assessment, Auditing and Monitoring**

EdgeEndo® periodically assesses the risk of misconduct and takes reasonable measures to design, implement, or modify each element of the compliance program, as required. The Ethics & Compliance team conducts a risk assessment using a risk-based approach. EdgeEndo® conducts compliance audits periodically to evaluate adherence to the Company's standards. The Company also monitors for new and emerging risk areas on an ongoing basis. The nature of our reviews, as well as the extent and frequency of our compliance monitoring and auditing, varies according to a variety of factors, including new regulatory requirements, changes in business practices, and other considerations.



## Enforcement and Disciplinary Measures

We conduct fair, diligent and timely investigations of reports of potential non-compliance that are brought to the Company's attention. EdgeEndo® takes disciplinary actions, where appropriate, in response to confirmed violations of the Company's standards, and strives to ensure consistent application of the Company's standards. Responses to Detected Problems and Corrective Actions An effective compliance program increases the likelihood of preventing and detecting unlawful and unethical behavior. However, even an effective compliance program may not prevent all violations. Accordingly, the Company's Comprehensive Compliance Program requires a prompt response to potential violations of law, standards or Company policy. Actions in response to detected problems, and to prevent future violations, may include improving policies or procedures, training, communication and monitoring or disciplinary action.

## DECLARATION OF COMPLIANCE WITH CALIFORNIA HEALTH AND SAFETY CODE §§119400-119402

EdgeEndo® has adopted a Comprehensive Compliance Program guided by OIG's Compliance Program Guidance for Pharmaceuticals and industry standards. We tailored our Comprehensive Compliance Program to the nature of our business as a manufacturer and distributor of dental and medical products. The California law makes reference to compliance with the PhRMA Code on Interactions with Healthcare Professionals (PhRMA Code), which is an industry standard that applies to pharmaceuticals and does not reflect the unique nature of manufacturer and distributor activities. We have, accordingly, not adopted the PhRMA Code, but instead have adopted a marketing code of conduct intended to help ensure our compliance with applicable laws and regulations and consistent with industry standards for manufacturers and distributors. We believe that EdgeEndo® has developed a Comprehensive Compliance Program that meets the compliance goals set forth by California Health and Safety Code sections 119400 through 119402. To our knowledge, we are, in all material respects, in compliance with our Comprehensive Compliance Program and the requirements of California Health and Safety Code sections 119400 through 119402, as we interpret and apply the requirements to the nature of our business. Although we are not making a representation that every employee and agent will always fully comply with our standards and rules, our Comprehensive Compliance Program is reasonably designed to prevent and detect violations. We are committed to monitoring our conduct and taking appropriate action to discipline Company personnel who violate our standards. Copies of this declaration and the above description of our Comprehensive Compliance Program may be obtained by calling EdgeEndo® Compliance Helpline: 1-877-285-4157 (for the United States and Canada) or by visiting the company website.

Dated: June 3, 2024