

# Leica Microsystems California Comprehensive Compliance Program and Compliance Declaration

March 2023

NOTICE: Leica Microsystems is providing this information pursuant to the requirements of California Health and Safety Codes §§119400-119402 (the "Statute"), which requires certain medical device companies doing business in California to make available their Compliance Program and annual written Declaration of compliance with the Compliance Program.

The Description and Declaration below covers Leica Microsystems.

## I. INTRODUCTION

Leica Microsystems (hereinafter "LMS") is committed to doing business in accordance with the highest standards of business conduct and ethics, and we consider our reputation for ethical and compliant behavior to be a valuable corporate asset. Accordingly, LMS has established a comprehensive Compliance Program in accordance with California Health and Safety Code, Division 104, Part 15, Chapter 8, Sections 119400-119402 (the "Statute"), based on our good faith understanding of the requirements of the Statute as it may apply to a medical device manufacturer, and the Compliance Program Guidance for Pharmaceutical Manufacturers ("OIG Guidance") published by the Office of Inspector General, U.S. Department of Health and Human Services.

Our Compliance Program, applied in conjunction with our MedTech Healthcare Professional Engagement Policy ("MedTech Policy"), is tailored to LMS's size, organizational structure, available resources, and the nature of our business as a medical device manufacturer. The medical device industry has established, and LMS's Compliance Program is designed in accordance with, the AdvaMed Code of Ethics on Interactions with Health Care Professionals (the "AdvaMed Code"). The AdvaMed Code is a voluntary ethical code substantially similar to the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals (the "PhRMA Code") but was developed with a primary focus on the unique interactions between medical device manufacturers and healthcare professionals and is thus more uniquely suited to LMS's compliance needs.

This is a description of LMS's comprehensive Compliance Program. It reflects the plan and policies we have implemented, but LMS's Compliance network is a dynamic and continuously developing entity requiring coordination between multiple policies and programs as well as the commitment of our management team and associates. While adoption and implementation of appropriate policies cannot guarantee complete elimination of improper conduct, it is LMS's expectation that all associates will comply with our Compliance Program and all applicable laws, rules, and regulations. To our

knowledge, we are, in all material respects, in compliance with our Compliance Program and applicable law. LMS's passion for continuous improvement in all areas of our business dictates that we regularly review and enhance our Compliance Program to adapt to our evolving compliance needs.

## **II. DESCRIPTION OF COMPLIANCE PROGRAM**

### **A. Leadership and Structure**

Our Compliance Program has been developed by LMS's Compliance leadership and is managed by Urte Kristina Wendt, LMS Global Compliance Director. LMS Senior Management works with the Compliance team to ensure LMS effectively prevents, detects, and reacts to instances of non-compliance.

### **B. Policies and Procedures**

LMS has adopted written policies and procedures such as our MedTech Policy to implement our high ethical standards and meet our healthcare compliance obligations under applicable laws, regulations, and industry codes of conduct. These policies apply to all LMS associates and compliance with those policies is a condition of employment.

LMS, in accordance with California law, has established an annual limit on promotional spending of USD \$5000 per individual California medical and health professional, which includes persons licensed by California to prescribe prescription products, medical students, and members of drug formulary committees. This limit covers gifts, promotional materials, or items or activities that LMS may give or otherwise provide to an individual medical or healthcare professional in California. This limit represents a spending cap and not an average or target, and in most instances the amount spent per physician will be substantially less than this annual limit.

The annual limit excludes non-promotional spending such as: drug samples or demonstration units; financial support for continuing medical education forums or health education scholarships if provided in accordance with LMS policy; fair market value compensation for bona fide professional services, and any meals or other expenses related to the provision of such services; training programs necessary for the safe and effective use of LMS products; items of nominal value with a retail value of less than \$10.

### **C. Training and Education**

We regularly provide compliance training to all LMS associates, including new hire compliance training. We provide courses on ethics as well as LMS's Compliance Program and MedTech Policy to all sales, marketing and research and development associates, both as a part of a regular training program and ad hoc as needed.

#### D. Compliance Communications

Our Company is committed to maintaining a work environment where all individuals encourage and embrace open discussion across both geographical and operational boundaries. Employees are encouraged to seek guidance in resolving ethics and compliance questions. They are required to report suspected or actual unethical or non-compliant conduct, violations of law or regulation, and violations of internal company policies. LMS associates are encouraged to use our reporting hotline which allows anonymous reporting of suspected or actual noncompliance without retaliation.

#### E. Auditing and Monitoring

Our Company performs compliance gap analyses, process reviews and data analysis to identify and address potential issues and opportunities to enhance its processes and practices. These are collaborative efforts between the Compliance Department and the business which has generated the development of new and revised policies, new training and communications initiatives and corrective action.

#### F. Investigating and Responding to Potential Violations

Our Compliance Department monitors company functions and activities for potential violations of law, regulation, industry codes, the Code of Conduct and company policies. Potential violations are promptly and thoroughly investigated and appropriate corrective action taken.

#### G. Corrective Action

In determining the appropriate response to an established violation, our Company considers various options for corrective action. These options include remediation to evaluate current practices and close any gaps in policies, practices or training that may have led or contributed to the violation, as well as the imposition of disciplinary action up to and including termination. In situations that call for it, LMS will not hesitate to notify appropriate law enforcement agencies of criminal or otherwise illegal activity.

A copy of this description of LMS's Compliance Program and Declaration may be obtained by calling (800) 248-0123.