

Annual Declaration of Compliance – California Health and Safety Code § 119402
March 19, 2016

Ablative Solutions, Inc. (“ASI”) is committed to meeting the highest standards of ethics in its corporate conduct. To that end, and in accordance with the requirements of California Health and Safety Code § 119402, ASI has adopted a Comprehensive Compliance Program (“CCP”) that is in accordance with the “Compliance Program Guidance for Pharmaceutical Manufacturers” issued by the Department of Health and Human Services Office of Inspector General in 2003 (“HHS-OIG Guidance”). As part of its CCP, ASI has established an annual per-practitioner spending limit of \$1,500 for certain promotional activities directed toward healthcare professionals practicing in California. As of the date of this declaration, ASI declares that, to the best of its knowledge and based on a good faith understanding of the requirements of the statute, it is in compliance with its CCP and with California Health and Safety Code § 119402, in all material aspects.

Consistent with the HHS-OIG guidance, ASI has adopted a CCP that is designed to fit the size and structure of the company and is regularly reviewed to ensure that the CCP still meets applicable legal and ethical requirements. In particular, the CCP is designed to meet requirements that are applicable to a medical device manufacturer. The medical device industry has established the Advanced Medical Technology Association Code of Ethics on Interactions with Healthcare Professionals (“AdvaMed Code”), which is substantially equivalent to the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals, but with a particular emphasis on the issues most relevant to interactions between medical technology companies and healthcare professionals. Accordingly, ASI has included in its CCP policies for compliance with the AdvaMed Code.

The company’s CCP consists of seven key elements, as described in further detail in ASI’s Compliance Program Overview and in other policies and procedures adopted by the company:

- Written policies and procedures for compliance with applicable laws and regulations
- Leadership responsibility for compliance operations
- Education and training of company personnel on compliance
- Enabling communication and investigation of potential misconduct
- Responding effectively to violations, including through appropriate discipline
- Regular monitoring of compliance
- Continued development and refinement of the compliance program

A copy of this document and/or ASI’s CCP may be obtained by calling toll free 1-855-295-4619. You may also submit questions regarding ASI’s CCP or request a copy of this document by writing to compliance@ablativesolutions.com.