



## **STATEMENT AND DECLARATION OF COMPLIANCE WITH CALIFORNIA LAW**

Effective September 2, 2016, to the best of our knowledge, Balt USA, LLC (“Balt USA”) is in all material respects in compliance with a Comprehensive Compliance Program (“CCP”) that satisfies the requirements of California Health and Safety Code §§ 119400-119402, based on our good faith understanding of the statutory provisions as they may apply to a medical device manufacturer.

Consistent with the Department of Health and Human Services Office of the Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers (“HHS-OIG Guidance”), Balt USA has tailored its CCP to the nature of its business as a medical device manufacturer. While California Health and Safety Code §§ 119400-119402 makes reference to compliance with the Pharmaceutical Research and Manufacturers of America’s Code on Interactions with Healthcare Professionals (“PhRMA Code”), Balt USA manufactures medical devices rather than pharmaceutical products. Therefore, Balt USA determined that it was more appropriate for the company instead to adopt policies and procedures consistent with the AdvaMed Code of Ethics on Interaction with Healthcare Professionals (“AdvaMed Code”) which, although substantially similar to the PhRMA Code, recognizes significant differences applicable to the medical device industry.

Balt USA is committed to the highest standards of ethical and legal conduct. We have developed a CCP that is reasonably designed to prevent and detect violations, and discipline employees as necessary. The CCP is a fluid and ever-changing program that is designed to meet the evolving regulatory and legislative climate. This program will be assessed on an annual basis.

This declaration is made as of September 2, 2016.

To obtain a print version of our CCP or this declaration, please call the Quality Assurance and Regulatory Affairs Department at (949) 788-1443, or by emailing [customerservice@balt-usa.com](mailto:customerservice@balt-usa.com).

### **Balt USA**

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