



BIOLASE Technology, Inc.
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Biolase Technology, Inc. is aware that certain "third-party" dental laser manufacturers and service suppliers are refurbishing or redesigning Biolase dental laser products and accessories for resale. These third-party companies are also offering services for repair, refurbishment and upgrades to Biolase products purchased by previous Biolase customers. Please be advised that those third-party suppliers may not have been trained by, and are not sanctioned by, Biolase to perform these design and manufacturing operations.

Please also be advised that any unauthorized modification to a Biolase product or accessory voids any warranties in place, and Biolase disclaims any and all liability relating to the use of such products. Unauthorized and unvalidated changes, revisions or upgrades to instrument software and hardware may result in serious harm and/or injury to patients undergoing dental procedures.

U.S. Federal Regulations (21 CFR Part 820, Quality System Regulation) govern the manufacturing and importing of all medical devices in the United States. These regulations require that all companies engaging in the design, manufacture and marketing of medical devices (i.e., dental laser systems) must go through a FDA pre-market notification and approval process before such products may be legally sold and distributed within the United States. These requirements also apply to refurbishers and remanufacturers of medical devices, especially if new claims are made for those devices. Medical devices that are produced outside of U.S. Federal Regulations may be considered by the FDA to be "adulterated."

If you have any questions, concerns or suggestions, please do not hesitate to call me at 949-226-8698. Thank you for your consideration.

Sincerely,

A handwritten signature in blue ink that reads "Gustavus D. Bock". The signature is fluid and cursive, with a large initial "G" and "B".

Gustavus Denton Bock
Vice President, RA/QA, Compliance
Biolase Technology, Inc.