



## **CERTIFICATION OF COMPLIANCE**

IsoTis/Integra OrthoBiologics, Inc., Bioimplants contain human tissue supplied by tissue banks that are accredited by the American Association of Tissue Banks (AATB).

These products consist of human tissues that are subject to the regulatory requirements established Under Title 21 of the Code of Federal Regulations, Part 1270 (21 CFR 1270), *Human Tissue Intended for Transplantation* and Part 1271 (21 CFR 1271) *Human Cells, Tissues and Cellular and tissue-based Products; Establishment Registration and Listing*. The FDA's requirements pertain to donor screening and testing; tissue processing, storage, and distribution; and documentation and record keeping.

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