

## > REGULATORY COMPLIANCE

Tissue Genesis, an emerging leader in adipose-derived cell therapy and regenerative medicine, is committed to ensuring its products meet and—where possible—exceed all applicable regulatory requirements.

Tissue Genesis expects all of its products meet the highest standards of safety, integrity and quality, and that all regulatory requirements are strictly fulfilled.

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### > REGULATORY COMPLIANCE AT TISSUE GENESIS - A CLOSER LOOK

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Tissue Genesis complies fully with all domestic and international regulations related to manufacturing of medical devices, including:

FDA regulations related to ensuring the adequacy of quality systems involved in the manufacture of medical devices and pharmaceutical products (reference US FDA's Code of Federal Regulations (CFR) part 820)

International Organization for Standardization (ISO) regulations related to customer satisfaction and quality management in the medical device industry (reference numbers 9001:2000 and 13485:2003)

Tissue Genesis ensures full compliance through the company's own rigorous internal audit program. Tissue Genesis also retains independent, external auditors to periodically evaluate the company on all regulatory compliance matters.

Additional audits are performed as part of Tissue Genesis' ISO certifications through its ISO registrar KEMA, one of the most experienced certification organizations in Europe and a leading global authority in testing and certification.

Tissue Genesis performs ongoing training and education for all of its employees as part of its commitment to fulfilling all regulatory compliance requirements.

Tissue Genesis is engaged in continual improvement, constantly updating its procedures to ensure both existing and new regulatory compliance issues are met.

Thanks to Tissue Genesis' relentless commitment to regulatory compliance, customers are assured that the company's products meeting the highest safety and quality standards set by respected domestic and international regulatory agencies.

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### > ABOUT TISSUE GENESIS

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An emerging leader in adipose-derived cell therapy and regenerative medicine, **Tissue Genesis, Inc.** is a high-growth, clinical-stage company based in Honolulu, Hawai'i. Industry-leading engineers and scientists have developed a proprietary process for Tissue Genesis that promote innovative medical solutions for a wide range of existing medical problems, including: cardiac and peripheral vascular disease; orthopedic injuries; aesthetic and soft tissue defects; and many other applications.

Thanks to Tissue Genesis, it is believed smart, safe and ethical regenerative therapies will improve the quality of life for patients and their families. For more information, please visit [www.tissuegenesis.com](http://www.tissuegenesis.com).

[tissue genesis inc.](http://www.tissuegenesis.com)

An Emerging Leader in Adipose-Derived Cell Therapy and Regenerative Medicine

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