Certificate of Compliance

(COC-0003, Rev 05)

This is to certify that TissueTech, Inc. (parent company of Amniox Medical, Inc. and Bio-Tissue, Inc., from hereon, collectively referred to as 'the Company') is a provider of 361 'Human Cells, Tissues and Cellular and Tissue Based Products' (HCT/Ps) for Amniox Medical, Inc. TissueTech, Inc. meets the requirements of the United States Food & Drug Administration (FDA) for the manufacture and distribution of Neox® 100, Neox Cord 1K®, Neox Cord RT, Neox FLO, Clarix® 100, Clarix Cord 1K and Clarix FLO (HCT/Ps) specified in Current Good Tissue Practices (21 CFR Part 1271), FDA Guidance Documents & current AATB Standards. TissueTech, Inc. certifies that:

- ✓ The Company is registered as a manufacturer and distributor with products listed with the US FDA *(available upon request)*
- ✓ Neox 100, Neox Cord 1K, Neox Cord RT, Neox FLO, Clarix 100, Clarix Cord 1K and Clarix FLO are designated by the FDA as Tissue Products (HCT/Ps)
- ✓ The Company is accredited by the American Association of Tissue Banks (AATB) *(available upon request)*
- ✓ The Company contracts directly with qualified procurement agent(s) *(available upon request)* for the acquisition of Birth Tissue (Placenta, Amnion and Umbilical Cord) and does not second source tissue or products
- ✓ Tissue is acquired after elective C-section from mothers birthing live, healthy babies
- ✓ The Company's facilities and Quality Systems are periodically inspected by the FDA and/or by qualified external auditors
- ✓ The Company is licensed by the New York State Department of Health *(available upon request)*
- ✓ The Company is registered with Health Canada respecting the Safety of Human Cell Tissues and Organs for Transplantation for all Amniox products, excluding Neox FLO and Clarix FLO *(available upon request)*
- ✓ The Company is licensed by the California State Department of Health *(available upon request)*
- ✓ The Company is registered with Maryland, Illinois & Oregon *(available upon request)*
- ✓ The Company is compliant with AATB and FDA guidelines for tissue processing
- ✓ The Company has been issued a waiver by the State of Florida exempting registration and certification as a tissue bank since the Company does not procure, process, store or distribute cadaveric tissue *(available upon request)*

Product Description: Neox 100, Neox Cord 1K, Neox Cord RT, Neox FLO, Clarix 100, Clarix Cord 1K and Clarix FLO are Amniox Medical's trademarks for processed human Amniotic Membrane and Umbilical Cord tissue retrieved from donated birth tissue after elective Cesarean Section delivery. These Amniotic Membrane and Umbilical Cord products are currently designated by the FDA as tissue products under PHS Act 361 HCT/P (human cells, tissues and cellular and tissue-based products). The cell activity of these tissues has been inactivated to reduce the possibility of graft rejection while retaining the natural biologic properties.

Tissue Place of Origin: Human Amniotic Membrane and Umbilical Cord tissues are only retrieved from donors within the United States who have donated tissue after elective Cesarean Section delivery.

Donor Suitability, Selection & Testing: Birth tissue is recovered aseptically after elective Cesarean Section from mothers birthing live, healthy babies. Mothers donate the tissue under full informed consent. The mothers are screened at delivery for infectious, malignant, neurological and auto-immune diseases and other exposures or social habits to determine the suitability for human transplantation. The suitability of the donation is determined by reviewing medical records and history of possible transmissible diseases (via a standard questionnaire) and reviewing physical examinations that have been performed. Mothers are also serologically tested by an independent CLIA-certified lab at the time of delivery and must be found non-reactive using FDA-licensed, approved or cleared test kits for the following tests:

- HIV 1 (NAT-RNA)
- HIV 1 & 2 (antibody)
- Hepatitis B (NAT)
- Hepatitis B surface antigen (HBsAg)
- Hepatitis B core antibody (HBcAb)
- Hepatitis C Antibody (HCVAb)
- Hepatitis C antibody, HCV (NAT-RNA)
- HTLV 1 & 2 antibodies
- Syphilis
- West Nile Virus (WNV, RNA-NAT)

Process Controls: Final product is processed for Amniox Medical in the Company's GMP Clean Room Facility using aseptic methods under ISO Class 5 Biological Safety Cabinets. Final product (Neox 100, Neox Cord 1K, Clarix 100 and Clarix Cord 1K) is tested by an independent CLIA-certified lab and is released once microbiological testing for aerobic, anaerobic and fungal organisms shows no growth. Final product (Neox Cord RT, Neox FLO and Clarix FLO) is released after sterilization by gamma irradiation to a Sterility Assurance Level (SAL) of 10^{-6}. Additionally, technical review and Quality Assurance approval is performed before product release. Process validations of aseptic processing, container and integrity testing of the final packaging system, final product sterilization (for Neox Cord RT, Neox FLO and Clarix FLO products), and antimicrobial effectiveness of the final packaging system have been performed and found the systems and processes to be acceptable. With the exception of the human tissue, all materials and reagents used to process the tissue products are sterile.

Labeling & Tracking: Each finished product (HCT/P) is assigned and labeled with a unique identification code that relates the final product to the donor. There is a system established and maintained to track the final product from the consignee to the donor and from the donor to the consignee or final disposition.

CRYOTEK® CRYOPRESERVED PRODUCTS

Stability/Solutions (Cold Storage): Amniox Medical's Amniotic Membrane and Umbilical Cord products (Neox 100, Neox Cord 1K, Clarix 100 and Clarix Cord 1K) are preserved in a validated storage medium made of Dulbecco's Modified Eagle Medium and Glycerol (1:1) containing Amphotericin B. Cryopreservation is vital for maintaining the integrity and biologic activity of Amniotic Membrane and Umbilical Cord: Validation studies have been conducted to establish the expiration date of these Amniotic Membrane and Umbilical Cord products at temperatures between -80°C and 4°C and the results are reflected in the storage requirements established for these products. Validation studies included analysis of frozen sections followed by morphological staining of test and control tissue samples, as well as package and container closure integrity validation of final packaging systems.

Packaging/Shipping (Cold Storage): See individual Product Inserts for packaging information. The shipping containers (NanoCool systems) have been validated via simulated and actual shipping condition testing. The validation studies concluded that the shipping containers currently in use by the Company for final product distribution and shipment effectively maintain temperatures below 21°C for up to 72 hours when tested against the ISTA-7D seventy-two-hour summer profile (standard shipper) and for up to 96 hours when tested against the ISTA-7D seventy-two hour (modified to 96 hours) summer profile (long haul shipper). These studies also provide objective evidence that the package integrity is maintained throughout transit, therefore providing sufficient protection to the product during the transportation process.

Storage (Cold Storage): Amniox Medical's Cryopreserved Amniotic Membrane and Umbilical Cord products (Neox 100, Neox Cord 1K, Clarix 100 and Clarix Cord 1K) are stored at -80°C (-112°F) before shipping to retain their natural function and integrity. These Cryopreserved Amniotic Membrane and Umbilical Cord products are shipped in validated NanoCool shipping systems. If the unit is not used immediately, the following guidelines should be followed for the storage of the Amniox Medical's Cryopreserved Amniotic Membrane and Umbilical Cord products:

Usage after receipt of Tissue	Storage Temperature	Acceptable Storage Location	Storage Time
Few hours after package arrival	Below 21°C (Below 69.8°F)	Unopened insulated shipping container (NanoCool)	Within the expiration date on outer shipping box
Long Term Storage	-80°C → 4°C (-112°F → 39.2°F)	Ultra-low Temperature Freezer, Standard Freezer, or Standard Refrigerator	Within the expiration date printed on product packaging (shelf-life is 2 years from date of manufacture)

Amniotic Membrane and Umbilical Cord products exposed to controlled room temperature (20°C to 25°C, 68°F to 77°F) for up to 6 hours may be returned to cold temperature storage in accordance with the storage table above as long as the packaging remains unopened and intact.

STERILE MICRONIZED PRODUCTS

Stability (Ambient): Amniox Medical's sterile micronized Amniotic Membrane and Umbilical Cord products (Neox FLO and Clarix FLO) are packaged and sealed in a validated final packaging system. The tissue has been stored at ambient room temperature prior to distribution. Validation studies have been conducted to establish the expiration date of these micronized - Amniotic Membrane and Umbilical Cord products at ambient storage and those results are reflected in the storage requirements established for these products. Validation studies included analysis of the product integrity as indicated by its biological function of test and control tissue samples.

Packaging/Shipping (Ambient): See individual Product Inserts for packaging information. The shipping containers have been validated via simulated transit testing in accordance with ISTA 6-FedEx-A <50lbs., 2007 Standards. The validating studies concluded that the shipping containers currently in use by Amniox Medical for final product distribution and ambient shipment effectively maintain package integrity throughout the transit, thereby providing sufficient protection to the product during the transportation process.

Storage (Ambient): Amniox Medical's sterile micronized Amniotic Membrane and Umbilical Cord products (Neox FLO and Clarix FLO) are gamma irradiated to an SAL of 10^{-6} and stored at ambient room temperature before shipping. These micronized Amniotic Membrane and Umbilical Cord products are shipped in validated shipping containers. If the unit is not used immediately, the following guideline should be followed for the storage of Amniox Medical's micronized Amniotic Membrane and Umbilical Cord products:

Storage Temperature	Acceptable Storage Location	Storage Time
0°C ➔ 38°C (32°F ➔ 100.4°F)	Ambient Environment	Until the expiration date printed on outer product packaging (shelf life is 2 years from date of manufacture)

STERITEK® STERILE ROOM TEMPERATURE PRODUCTS

Stability (Room Temperature): Amniox Medical's sterile Umbilical Cord graft products (Neox Cord RT) are packaged and sealed in a validated final packaging system. The tissue has been stored in controlled room temperature prior to distribution. Validation studies have been conducted to establish the expiration date and sterility assurance level (SAL) of 10^{-6} of these Umbilical Cord products at controlled room temperature; those results are reflected in the storage and sterility requirements established for these products. Validation studies included analysis of the product integrity as indicated by its biological function of test and control tissue samples.

Packaging/Shipping (Room Temperatu re): See individual Product Inserts for packaging information. The shipping containers have been validated via simulated transit testing in accordance with ASTM D4169 Standard Practice for Performance Testing of Shipping Containers and System. The validation studies concluded that the shipping containers currently in use by Amniox Medical for final product distribution and shipment effectively maintain package integrity throughout the transit, thereby providing sufficient protection to the product during the transportation process.

Storage (Room Temperature):

Storage Temperature	Acceptable Storage Location	Storage Time
20°C ➔ 25°C (68°F ➔77°F)	Controllred Room Temperature Environment	Within the expiration date printed on product packaging (shelf-life is 2 years from date of manufacture)

Voluntary Correction/Removal Procedures: The Company has detailed procedures in place to respond appropriately to product concerns that may affect the health and safety of the patient. The current tracking system facilitates any correction or removal event that may occur. All affected customers will be immediately notified by verbal or electronic communication. Formal written notification will also be issued.

Refer to Amniox Medical's Amniotic Membrane and Umbilical Cord Individual Product Inserts for more details.