Aorta: The larger portion of the body in a woven vascular graft, representative of a portion of the large artery that begins at your heart and runs through your abdomen.

ATEX Document Management System (ADMS): A depository for all ATEX generated documentation that is used to manufacture products and the “Go To” place for all information about how a part is made.

ATEX part #: The part number assigned by R&D during original setup. This stays with the product forever.

Audit: Review of any portion of the quality management system; designated as formal or informal: See also Internal Quality Audit.

- **Formal**: A documented review of a QSP section or process outlined in a WI.
- **Informal**: A non-documented review of any QSP section or process outlined in a WI.

Backwinding: Rewinding yarn or fiber from one type of package to another; to break down a large package into smaller packages.

Bar Code: Adjacent stripes of varying width used to represent alphanumeric characters. These permit rapid reading by means of electronic scanners.

Beam: A horizontal cylinder usually of metal on which a large number of yarns are wound in a side by side arrangement in preparation for weaving or warp knitting.

Bifurcated: Woven grafts that are split or divided into two portions or branches are called bifurcated. The bifurcated portion is representative of the iliacs, sometimes referred to as the legs of a woven vascular graft.

Bifurcate graft (BIF): A woven tube with a single diameter on one end and two smaller diameters on the other end.

Body: A single diameter tube portion of a bifurcate or taper graft

Braiding mandrel: Rigid material to braid on top of to give desired diameter

Broken End: A broken, untied warp thread in a fabric


Burst Strength (Truburst): the strength of a fabric in all directions, tested on Truburst machine.

Carrier: In braiding process, the mechanism that carries one bobbin through the cycle.

Certificate of Analysis (COA) System: The Certificate of Analysis application is a Microsoft Visual Basic 2005 program developed for ATEX Technologies. The application creates documents that provide the inspection and test results of the product being shipped to the customer.

Characteristics: A distinguishing feature, dimension or property of a process or product on which data can be collected. Circumference: Perimeter line bounding any circle.

Cone Gage: A gage used in QA Testing to measure the diameter of a tube.

Controlled Environment: An environment in which effects such as humidity, pressure, temperature, etc., are maintained at predetermined levels and which prevents outside contaminants from coming into contact with the product.

Courses: The row of loops or stitches running across a knitted fabric.
Courses per inch (CPI): The number of horizontal rows of loops in an inch of knitted fabric.

Covering: The process of wrapping one yarn around another

Cut (In Warping): Gash in the beam barrel or flange caused by a knife during the yarn removal process.

Cut Part (knitted): In the fabrication process a part that is cut from a knitted panel.

Cutting: The process of separating a knitted fabric roll into separate fabric panels

Cutting Frame: A tool used in the fabrication process to final cut parts to length (large quantities per cut)

D

Defect: A general term that refers to some flaw in the fabric that detracts from either performance or appearance properties.

Density: EPI (Ends per Inch) x PPI (Picks Per Inch)

Dent: A space on a reed or a sley between two dent wires where the yarn lies.

Design History File (DHF): A compilation of records which describes the design history of the finished part (i.e. design input, design output, design/project plan, design reviews, design verification). The launch folder serves as the DHF at ATEX.

Die: The frame or cutting template used in the die press to cut fabric panels into shapes, sizes, or lengths as required by the customer on the Design Specifications.

Die Cut: The process of cutting a product to the dimensions required by the customer on the Design Specifications.

Die Cut Press: At ATEX the machine used to cut fabric panels into the dimensions required by the customer on the Design Specifications. The die and material to be cut are placed in the press and the final shape is stamped out.

Dobby: A mechanical attachment on a loom that controls the harness to permit the weaving of geometric figures.

Dobby Loom: A weaving machine with harness frames and limited design capability can make seamless tube.

Double End: Two ends woven as one in a fabric.

Drawing-In: In weaving the process of threading warp ends through the eyes of the heddles and the dents of the reed. The process of pulling the warp yarn into the weaving machine one end at a time (through heddles).

Dropped End Seam: A patented ATEX technology that “drops” out ends in the taper area to create bifurcates and tapered grafts.

E

End: An individual warp yarn.

End Out: A void caused by a missing warp yarn.

Ends Per Inch (EPI): The number of vertical rows of in an inch of woven fabric

F

Fabrication (FAB): ATEX department or area that processes and inspects greige fabric from knitting and weaving according to customer and conformance specifications.
Fabrication Work Order: A controlled document instructing the technician the process that needs to be completed on a specified product.

False Twisting: See TEXTURING, False-Twist Method

False-Twist Method: This continuous method for producing textured yarns utilizes simultaneous twisting, heat-setting, and untwisting. The yarn is taken from the supply package and fed at controlled tension through the heating unit, through a false-twist spindle or over a friction surface that is typically a stack of rotating discs called an aggregate, through a set of takeup rolls, and onto a take-up package. The twist is set into the yarn by the action of the heater tube and subsequently is removed above the spindle or aggregate resulting in a group of filaments with the potential to form helical springs. Much higher processing speeds can be achieved with friction false twisting than with conventional spindle false twisting. Both stretch and bulked yarns can be produced by either process. Examples of false-twist textured yarns are Superloft®, Flufflon®, and Helanca®. (Also see TEXTURED YARNS, Coil Yarn.)

Float: A fabric defect consisting of an end lying or floating on the cloth surface instead of being woven in properly.

Fourth Shift: An enterprise planning resource system that logs transactions and holds information in an integrated database. Fourth Shift responsibilities include the assignment of identification numbers, receipt of purchase orders, assignment of work orders, and handling all transactions regarding manufacturing status, warehouse location and shipping.

Fuzz Ball: A defect in which loose or frayed fibers form into a ball and are then woven into the fabric.

G

Graft: A woven tubular product that is used for vascular reconstruction.

Greige Fabric: An unfinished fabric just off the loom or knitting machine.

Greige Panel: A knitted unit of fabric that has not been fabricated.

Guides: In knitting, a fitting that the yarn passes through in the machine.

Guide Bar: A mechanism on a warp-knitting machine that directs warp threads to the latch needles.

H

Harness: A frame holding the heddles in position in the loom during the weaving process.

Heddle: A cord, round steel wire, or thin flat steel strip with a loop or eye near the center through which one or more warp threads pass on the loom so that the thread movement may be controlled in weaving.

I

Iliacs: The bifurcated portion of a woven graft sometimes referred to as legs.

Implantable Medical Device: Medical device intended:
- to be totally or partially introduced into the human body or a natural orifice, or
- to replace an epithelial surface or the surface of the eye, by surgical intervention, and which is intended to remain after the procedure for at least 30 days, and which can only be removed by medical or surgical intervention.

Inspection: The process of examining products for defects at any stage of manufacturing or finishing.
Instruments: Any piece of measuring or test equipment, either mechanical or electrical, is referred to as an “instrument” in this procedure. (The definition includes “tool,” “gauge,” “test equipment” and “standards”).

IOQ- Installation and Operational Qualification: Often referred to as equipment qualification – a combination of IQ and OQ which is carried out for manufacturing and testing equipment whether the equipment is used as part of a special process or not. Calibration and maintenance specifics are an output of IOQ to ensure on-going performance of the equipment.

IQ – Installation Qualification: Defined requirements for installation of a piece of equipment, which includes a parts list and checklists to ensure all parts are present and have been properly connected. IQ addresses actions and checks prior to first turning the equipment on (examples include utilities connections, drainage, environment, ventilation).

ISO-13485: The internationally recognized standard for the requirements of a quality management system as set forth by the International Organization for Standardization (ISO) for the Medical Device industry.

Item Number: A number assigned to the customer product for identification purposes. May also be referred to as Part number and/or Style Number.

J

Jacquard: A system of weaving that utilizes a highly versatile pattern mechanism to permit the production of intricate designs.

K

Knit Fabric: A structure produced by interlooping one or more ends of yarn or comparable material. (Also see KNITTING.)

Knitting: A method of constructing fabric by interlocking series of loops of one or more yarns.

Knitting Machine: A machine that produces knit product.

L

Labelling: Written, printed or graphic matter
- affixed to a medical device or any of its containers or wrappers, or
- accompanying a medical device,
related to identification, technical description, and use of the medical device, but excluding shipping documents.

Life Cycle: The complete history of a system or process from its inception until it is no longer kept in service by a customer or user.

Light Box: A unitary box for inspecting fabric panels and woven grafts providing several angles of sight to the technician from the same vantage point so as to locate defects not ordinarily visible during conventional head on observation.

Loom: A machine for weaving fabric by interlacing a series of vertical, parallel threads (the warp) with a series of horizontal, parallel threads (the filling).

Lot: A unit of production or a group of units or packages.

Lot Number: Number assigned to a unit of production once it has been doffed or removed from the machine, also referred to as a doff number.
M

Mandrel: A cylindrical or symmetric shaft or form sometimes tapered or bifurcated constructed to the dimensions as required by customer design specifications that is used in the heat set process of woven vascular grafts.

Mispick: A weaving defect in which a pick is improperly interlaced, resulting in a break in the weave pattern.

N

Needle: The portion of a knitting machine used for intermeshing the loops.

Needle Loom: A machine for bonding a woven web by mechanically orienting fibers through the web.

O

On-Time Delivery: The measurement of acceptable delivery range from due date either by ATEX Technologies, Inc. of incoming raw material or by our customer for finished goods (handled by individual customer).

P

Part Number: A number assigned to the customer product for identification purposes. May also be referred to as Style number and or Item Number.

Pattern Chain: In knitting, a chain that is built to control the fabric design in the machine.

Permeability: The state or quality of being penetrable by fluids or gases.

Pick Count: The number of filling yarns per inch or per centimeter of fabric.

Pick Glass: An inspection tool that is used to magnify the product so that defects or abnormalities can be easily identified. It can also be used as a measuring device and as a tool when conducting a fabric count.

Picks: Individual filling yarns from the shuttle also known as weft.

Product Number: A number representing anything produced at ATEX to satisfy a customer’s requirement. May also be referred to as Item number, style number, or part number.

Products: Items that ATEX Technologies, Inc. sells to its customers and the materials and services acquired from suppliers or subcontractors that go into those items.

Product Specifications: Requirements provided by the customer for mandatory compliance.

Prototype: A sample of a finished product submitted to the customer for review and approval.

R

Raschel Knitting: A versatile type of warp knitting made in plain and Jacquard patterns; the latter can be made with intricate eyelet and lacy patterns and is often used for underwear fabrics. Raschel fabrics are coarser than other warp-knit fabrics, but a wide range of fabrics can be made. Raschel knitting machines have one or two sets of latch needles and up to thirty sets of guides.

Reed: A comb-like device on a loom that separates the warp yarns and also beats each succeeding filling thread against that already woven. The reed usually consists of a top and bottom rib of wood into which metal strips or wires are set. The space between two adjacent
wires is called a dent (or split) and the warp is drawn through the dents. The fineness of the reed is calculated by the number of dents per inch.

**Reed marks:** A fabric defect consisting of warpwise light and heavy streaks in a woven fabric, caused by bent, unevenly packed, or weak reed wires.

**Request for Quotation (RFQ):** A written or verbal request indicating a customer interest to purchase product from ATEX Technologies, Inc.

**S**

**Slub:** A yarn defect consisting of a lump or thick place on the yarn caused by lint or small lengths of yarn adhering to it. Generally, in filament yarn, a slub is the result of broken filaments that have stripped back from the end to which they are attached.

**Space:** The position on the loom where the product was woven. Example: Machine #300 has 10 spaces or positions. Graft #1 was woven and doffed from space 3.

**Spec Sheet:** A document that indicates the exact dimensions of a product and instructions related to a particular product.

**T**

**Taper:** the property or shape of a woven graft that narrows toward a point (as a wedge or cone).

**Tappi Chart:** A chart used for determination of defect size and to verify according to customer specifications and/or ATEX quality standards whether the product is acceptable or not acceptable.

**Tolerance:** Allowable deviation from standard: the permitted range of variation about a nominal value. The permitted tolerance is the difference between the upper and lower specification limits.

**Tooling:** Any piece of equipment such as molds or sealing tools used in the manufacture of components used in assemblies; also see Customer-Supplied Tooling.

**Traceability:** The ability to trace a product from beginning to end such as which machine produced the product and who ran the machine and on what date. Trace ability refers to the completeness of the information about every step in the life of a product from yarn production to finished product.

**V**

**Validation:** Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes.

**Vendor:** A supplier of products or services to ATEX Technologies, Inc. See also “Supplier.”

**W**

**Wales:** A column of loops lying lengthwise in a knitted fabric.

**Warp Beam:** A beam (large spool) that holds multiple ends of yarn to be woven or knitted. See also Beam.

**Warping:** The process of converting multiple packages of yarn into a single warp beam

**Warp Knitting:** A type of knitting in which the yarns generally run lengthwise in the fabric. The yarns are prepared as warps on beams with one or more yarns for each needle. Examples of this type of knitting are tricot, milanese, and raschel knitting.
Wash: The manner in which a soil, chemicals, or residue is removed from fabric panels or grafts prior to further processing.

Weaving: The process of interlacing two yarns of similar materials so that they cross each other at right angles to produce woven fabric.

Weft: Individual filling yarns from the shuttle, also known as picks.

**YARN Definitions**

D

Denier: Weight per unit length of yarn (g/9000m) or Weight in grams of any yarn 9,000 meters long. The lower numbers represent the finer sizes and the higher numbers the coarser sizes.

Denier per Filament: The denier of an individual continuous filament. In filament yarns it is the yarn denier divided by the number of filaments.

Draw-Texturing: In the manufacture of thermoplastic fibers, the simultaneous process of drawing to increase molecular orientation and imparting crimp to increase bulk.

Dtex: Weight in grams of any yarn 1,000 meters long.

E

Elongation: The deformation in the direction of the load caused by a tensile force. Elongation is usually expressed in percentage of the original specimen length.

F

FDY: Acronym for fully drawn yarn.

Filament: A fiber of an indefinite or extreme length such as found naturally in silk. Manufactured fibers are extruded into filaments that are converted into filament yarn.

Filament Count: the number of individual filaments that make up a yarn (multifilament or mono filament)

Filament Yarn: A yarn composed of continuous filaments assembled with or without twist.

Filling: In a woven fabric the yarn running from selvage to selvage at right angles to the warp. The filling yarn is carried by the shuttle. Each crosswise length is called a pick.

M

Mono Filament Yarn: Yarn composed of a single fiber.

Multi Filament Yarn: A yarn consisting of many continuous filaments or strands.

P

Package: An individual cone of yarn, May also referred to as a Pirn, tube, bobbin or Spool.

Polymer: A high molecular weight, chain like structure from which manufactured fibers derived; produced by linking together molecular units called monomers.
**Q**

**Quill:** A lightweight tapered tube constructed of either wood, plastic, or metal on which the filling yarn is wound for use in the shuttle during the weaving process.

**Quill Winding:** The process of winding filling yarns onto filling bobbins or quills in preparation for use in the shuttle for weaving.

**T**

**Textured Yarns:** Yarns that develop stretch and bulk on subsequent processing. Also see **TEXTURING.**

**Texturing:** The process of applying bulk to a yarn. The process of crimping, imparting random loops or otherwise modifying continuous filament yarn to increase cover or to provide a different surface texture.

**Titanium Dioxide:** A compound that occurs naturally in three different forms. It is used chiefly as a pigment or delusterant in paint or fiber.

**Twist:** The number of turns about its axis per unit of length of a yarn or other textile strand. Twist is expressed as turns per inch (tpi), turns per meter (tpm), or turns per centimeter (tpcm).

**Twist Direction:** The direction of twist in yarns and other textile strands is indicated by the capital letters S and Z. Yarn has S-twist if when it is held vertically, the spirals around its central axis slope in the same direction as the middle portion of the letter S, and Z-twist if they slope in the same direction as the middle portion of the letter Z. When two or more yarns, either single or plied, are twisted together, the letters S and Z are used in a similar manner to indicate the direction of the last twist inserted.

**Twisting:** The process of applying twist to yarn to increase strength and abrasion resistance holds multifilament yarn together.