SUPPLIER
QUALITY AGREEMENT

This Quality Agreement ("Agreement") is entered into as of _____ ("Effective Date") by and between _____, having a place of business at **EVS Supply, LLC** (referred to in this Agreement as "Buyer") and having a place of business at _____ (referred to in this Agreement as "Supplier") (individually, a "Party" and jointly, the "Parties")

1. Scope

This Agreement sets forth the mutually agreed upon expectations and obligations of Supplier with respect to the quality control, change control, non-conformance and related production activities of Supplier in supplying products to Buyer that Buyer utilizes in medical devices manufactured and produced by Buyer. For clarity, the term "manufacturer" as referred to in Chapter 21 of the CFR (or its foreign equivalents) and all requirements thereof, shall with respect to the products subject to this Agreement, mean Buyer.

This Agreement applies to all products purchased from Supplier by Buyer. Supplier shall comply with the terms and conditions set out in this Agreement for all products supplied to Buyer.

This Agreement shall take effect as an amendment to Service Agreement found via ("Standard Terms"). In the event any of the terms of this Agreement conflict with the Standard Terms, the terms of this Agreement shall prevail.

This Agreement and the quality requirements set forth in it are effective as of the Effective Date and shall remain in full force and effect for as long as Supplier provides products to Buyer. This Agreement may not be terminated earlier than or separately from any existing Purchase Agreement.

2. Definitions

Unless this Agreement expressly provides to the contrary, the following terms, whether used in the singular or plural, shall have the respective meanings set forth below:

2.1 *"Affiliate"*: a corporation or other business entity controlled by, controlling or under common control with a party. For this purpose "control" means that more than 50% of the controlled entity's shares or ownership interest representing the right to make decisions for such entity are owned or controlled, directly or indirectly, by the controlling entity.

2.2 "*Authority*": any government regulatory authority responsible for granting approvals for the performance of services under this Agreement or for the manufacturing, use, marketing, sale, pricing and/or other disposition of Buyer's product(s) in which the product(s) are used.

2.3 *"Advanced Product Quality Planning"*: is the system to communicate common product quality planning and control plan guidelines for suppliers to the automotive industry.

2.4 *"Approved Supplier List"* or *"ASL"*: the list of suppliers approved by Buyer to provide the materials specified in the bill of materials for a product.

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2.5 "*Buyer"*: the legal entity/person signing this agreement and any Affiliates that participate in this Agreement by issuing a Purchase Order.

2.6 "*CAPA System*": a Corrective Action and Preventive Action system for identifying and preventing or eliminating the cause of an existing or potential nonconformity, defect, or other undesirable situation in order to prevent occurrence or recurrence.

2.7 "*Certificate of Conformance*": a document, signed by an authorized representative of Supplier, attesting that a particular product is manufactured or serviced in accordance with applicable Quality Management System requirements, the specifications and this Agreement.

2.8 *"Certificate of Analysis"*: a document, issued by an appropriate Authority, that certifies the quality and purity of material used, documenting the analysis methods used and the results obtained. (Ref: ISO Guide 34-2000).

2.9 "*Certificate of Test*": a document, signed by an authorized representative attesting that identified product has been tested to identified test specifications and includes a conclusion regarding compliance with the test specification.

2.10 *"Component"*: any raw material, substance, piece, part, software, firmware, labeling or assembly which is intended to be included as part of the product(s) or consumed during the manufacture of the product(s).

2.11 *"Contact Matrix"*: a maintained list of individuals and their role / function that are responsible for the Buyer/ Supplier relationship. The Contract Matrix is not a Quality System Record.

2.12 "*Control Plan*": a document that identifies key manufacturing process steps, critical inputs to and critical variables of such steps, and that defines process monitoring control strategies and tools.

2.13 *"Correction(s)*": the repair, modification, adjustment, relabeling, destruction, or inspection of a device without its physical removal from its point of use to some other location.

2.14 *"Critical to Quality"* or "CTQ": the attribute or parameter specified by Buyer requiring special control. Supplier can provide input to the Buyer for CTQ requirements.

2.15 "*Device History Record*" or "*DHR*": a compilation of records containing the production history of the product(s).

2.16 *"Escape"*: a nonconforming product that has physically shipped from the Supplier. Escapes may be detected by Supplier or Buyer or third party. Nonconforming product that is identified during a Buyer performed source inspection is considered an Escape.

2.17 *"Field Action" (FA)"*: an activity outlining the steps for management of and/or communication regarding the performance of distributed clinical, custom, and/or market released product currently in use by the Buyer's end-user. These activities may include educational briefs, health safety alerts, notifications, corrections, removal, or recall of product(s) in any Buyer product(s).

2.18 *"ISO 13485*": the "ISO Quality Management Systems - Medical Devices - System Requirements for Regulatory Purposes" standard.

2.19 *"ISO 9001*": the "Quality Management Systems - Requirements" standard.

2.20 "*Lot*": one or more products manufactured under essentially the same conditions that are intended to have uniform characteristics and quality within specified limits.

2.21 *"Manufacturer"*: any person who manufactures, prepares, propagates compounds, assembles, or processes a device by chemical, physical, biological, or other procedure. The term includes any person who either:

i. Repackages or otherwise changes the container, wrapper, or labeling of a device in furtherance of the distribution of the device from the original place of manufacture;

ii. Initiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications;

iii. Manufactures components or accessories that are devices that are ready to be used and are intended to be commercially distributed and intended to be used as is, or are processed by a licensed practitioner or other qualified person to meet the needs of a particular patient

2.22 *"Manufacture(d)" a*nd *"Manufacturing"*: all steps, processes and activities necessary to produce product(s), including without limitation, the design, manufacturing, processing, quality control testing, release and storage of product(s).

2.23 *"Medical Device"*: an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

i. Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,

ii. Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

iii. Intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes

2.24 *"Nonconforming Product"*: any product that does not meet specified requirements.

2.25 *"Notified Body"*: an agency authorized by a competent authority that carries out conformity assessment procedures for some classes of medical devices.

2.26 *"Product" or "Products"*: all items and goods supplied or provided by Supplier to Buyer and includes service parts, materials, sub-assemblies, accessories or software incorporated in the products and the respective specifications and other requirements for the products, and any other items supplied by Supplier to Buyer.

2.27 *"Process Failure Modes And Effects Analysis"* or *"PFMEA"*: an analysis of potential failure modes within a process for classification by the severity and likelihood of the failures.

2.28 *"Purchase Order"*: any written or electronic purchase order issued by Buyer to Supplier for a product.

2.29 *"Product Submission Warrant (PSW)"*: the process used by Buyer to ensure that suppliers comply with all Buyer engineering design records and specification requirements.

2.30 "*Qualification*" (or "*Qualify*"): activity and analysis performed to demonstrate adherence to predetermined criteria. Qualification for a product means product testing or inspection conducted according to an approved and controlled protocol to ensure the product meets specifications.

2.31 "*Quality System*" or "*Quality Management System*" or "QMS": the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

2.32 "*Records*": written or electronic accounts, notes, data, record of, and information and results obtained from performance of activities of all work done under the Supplier's QMS.

2.33 *"Refurbished Material"*: used products or components that are re-used in the manufacture of new or modified products.

2.34 *"Removal"*: the physical removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection.

2.35 *"Rework"*: an activity performed to bring non-conforming product to conformance with the specification.

2.36 *"Service Part(s)"*: spare, repair or replacement parts, sub-assemblies or components for a product.

2.37 *"Services"*: the activities that Supplier is engaged in to provide products to Buyer under this Quality Agreement.

2.38 *"Specification(s)"*: the specifications, descriptions, design criteria, drawings, samples, prototypes, ASL and other requirements relating to the products provided in writing by Supplier or Buyer to the other from time to time to define the product(s).

2.39 *"Sub-tier Supplier"*: any supplier that either directly or indirectly provides product or service directly affecting product to the Supplier.

2.40 "*Supplier*": the legal entity party to this Agreement and its participating affiliates that provide product to a Buyer.

2.41 "*Validation*" (or "*Validate*"): confirmation by examination and provision of objective evidence that the applicable requirements can consistently be fulfilled.

3. Compliance with Applicable Quality Management System Requirements

3.1 Quality Management System Requirements

Supplier shall establish and maintain a Quality Management System that is appropriate for the activities for which the party is responsible under this Quality Agreement.

Products supplied under this Quality Agreement shall be manufactured in accordance with a Quality Management System compliant with:

- ISO 13485, including both EN (European) and Canadian CMDCAS, as necessary.
- MDD Council Directive 93/42 EEC and subsequent amendments, applicable annexes such as Annex II, V or VI, as necessary.
- FDA 21 CFR, as applicable

If certified, Supplier shall maintain the corresponding certificate issued by the accredited certification body. Upon request, Supplier shall provide Buyer copies of such certificates free of charge. Supplier shall notify Buyer of changes to the status of Supplier certificates that affect the status of any product or Quality System certification. Except as may be stated below, Supplier shall bear all costs associated with compliance with this section.

3.2 Specified Quality Provisions

Supplier shall comply with any quality provisions included in the specification documentation provided by Buyer. Supplier is to conduct a feasibility analysis in conjunction with the relevant department as directed by Buyer. Analyses may be conducted for new products, production or process modifications or large increases in volume and will evaluate given tolerances from a statistical point of view and establish whether Supplier has enough capacity to deliver the planned number of products and will be able to deliver the product within the specified deadlines. Possible feasibility analysis methods include:

- Design of Experiments (DoE)
- Failure Mode and Effects Analysis (FMEA)
- Process capability analysis (SPC)
- Design for Manufacturability (DFM) feedback
- Other information that demonstrates suppliers' overall capability to deliver products to specified quality levels

3.3 Management Responsibility

3.3.1 **Executive Representative:** Supplier shall assign a person or person(s) with executive responsibility, or who report(s) directly to a person with executive responsibility, to serve as a contact for Buyer under this Agreement, and to oversee compliance with this Agreement

3.3.2 **Personnel and Training:** Supplier shall have sufficient personnel with the necessary education, background, training and experience to perform the activities and obligations of this Agreement.

3.3.3 **Work Environment:** Supplier shall provide adequate resources, and ensure the responsibility, authority and interrelation of all personnel who manage, perform and assess work affecting product quality. This includes assigning an executive representative, ensuring personnel are adequately trained, and providing the appropriate work environment.

i. Supplier shall document and implement requirements for the control of health, cleanliness and clothing of personnel where contact between such personnel and the product or work environment could adversely affect the quality of the product.

ii. Where work environment conditions can adversely affect product quality, Supplier shall document and implement requirements for the work environment and procedures to monitor these work environment conditions.

iii. Supplier shall document and implement requirements for the control of contaminated or potentially contaminated product in order to prevent contamination of other product, the work environment, or personnel.

3.4 Control & Separation

Supplier shall ensure that product(s) and components are controlled and appropriately segregated during all stages of production and shipment to prevent mixing of accepted, unaccepted and non-conforming Product. Supplier shall have systems in place that provide a means of identifying conforming product ready for transfer to Buyer.

3.5 Traceability

Supplier shall be responsible for setting up and maintaining controlled documentation of product and component traceability during all stages of production and shipment. Traceability and quality records shall be maintained in accordance with record production and retention provisions in this Agreement.

3.5.1 **Minimum Traceability:** All products and components are traced by lot/batch, at a minimum.

3.5.2 **Each shipment shall include documentation that identifies:**

i. Supplier Name

ii. Purchase order reference

iii. Quantity released

iv. Buyer product part/model number including revision level

If applicable:

- Country of Origin
- Serialized product - The list of serial numbers included in that shipment.
- Lot controlled product – The list of lot number(s) included in that shipment and quantity included in each lot.
- Use By Date

3.5.3 **Process Information:** Process information is traced to all levels of the Supplier's assembly. This includes identification of the operator performing the operation, date identifying shift or time

performed, manufacturing instructions (including revision level) used, identification of relevant equipment used with traceability to equipment validation and calibration status, BOM/design revision and configuration, identification and resolution of any discrepancies, and record of any rework performed.

3.5.4 **Raw Materials/Components:** Documentation of raw material or component sourcing is to trace to the sourcing supplier's identifying lot/batch. Supplier shall ensure that sub-tier Suppliers comply with the equivalent of this provision.

3.6 **Corrective and Preventive Actions/Performance**

3.6.1 **Procedures:** Supplier shall establish documented procedures for establishing, implementing and maintaining an effective CAPA system in compliance with its Quality Management System. The CAPA system shall include, at a minimum, the following:

i. Analysis of quality data (e.g., Manufacturing processes, operations, quality audit records and reports, complaints, returned product) to identify root causes of Nonconforming Product or other quality problems. Supplier will employ appropriate statistical methodology where necessary to detect recurring quality problems.

ii. Investigation of the root causes of nonconformities.

iii. Identification of the actions needed to correct the nonconformance and to prevent recurrence.

iv. Verification or validation of the corrective and preventive action.

v. Implementation of and recording changes to methods and procedures needed to correct and prevent quality problems.

vi. Note: Prior notification and approval required by Buyer – see Section 6: Changes and Change Notification.

vii. Documentation of activities under the CAPA system.

viii. Effectiveness verification of corrective and preventive action.

3.6.2 **Resolution:** Supplier shall apply its CAPA system to any quality, manufacturing or performance issue raised by Supplier or Buyer related to product(s). Such activity may include making appropriate Supplier personnel available (at the Supplier's expense) at the Supplier and/or Buyer facilities where such product quality or performance or manufacturing issues are identified and/or need to be addressed within the timeframe requested by Buyer. Further, if Buyer believes in good faith that a product quality or manufacturing or performance issues of any Buyer devices that incorporates a Supplier's product is due to the product, then the Supplier shall at its own expense (i) conduct or have conducted a failure/root cause analysis, per its CAPA system, and (ii) provide Buyer with periodic reports commencing within 24-48 hours and with written report and all other information produced as a result of the failure/root cause analysis as soon as practicable but in any event within thirty (30) days after Buyer notifies a Supplier of such failure. In addition, Supplier shall inform Buyer in writing within two (2) business days after Supplier obtains knowledge of any actual or potential problems relating to the performance of any product manufactured for Buyer or any similar product manufactured by Supplier for a third party or any components or processes used in the product or substantially similar product if it relates to product already shipped or in

process. Supplier shall fully cooperate with all reasonable requests made by Buyer as to any such investigation.

3.6.3 **Field Actions:** Buyer has the sole authority for decisions related to any product(s) in the field, including any Field Action. Supplier shall support Buyer by providing access to necessary product information and quality records.

3.7 **Nonconforming Product**

3.7.1 **Control of Nonconforming Product:** Supplier shall have procedures to control product that does not conform to Buyer specified requirements. The procedures shall address the identification, documentation, evaluation, segregation, and disposition of Nonconforming Product, including a determination of a need for an investigation. These procedures shall be documented.

3.7.2 Where a product is identified by Buyer as Nonconforming Product, Supplier shall cooperate with Buyer in working to closure if a Non-Conformance Report (e.g. Quality Notification, Defect Report, etc.) and/or a Supplier Corrective Action Request (SCAR) is issued by Buyer.

3.7.3 **Product Performance:** Nonconforming Products may be returned to Supplier for investigation and analysis. In such cases, Supplier shall promptly notify Buyer when a Nonconforming Product is received. Supplier and Buyer shall also consult on the necessary analysis to be performed by Supplier. Supplier is responsible for analyzing material, investigating its own processes, and reporting results to Buyer within five (5) business days. Buyer also has the option to analyze the Nonconforming Product, andf Supplier shall cooperate with Buyer if Buyer exercises such option.

3.7.4 **Production Defects:** Production defects that exceed established Control Plan limits shall be investigated within Supplier's CAPA system. Supplier shall tabulate and analyze production defects for trends in order to identify need for further CAPA actions. These trends will be reviewed with Buyer during routine Business Management Review meetings.

3.7.5 **Escapes:** Supplier shall have control systems in place to prevent Escapes. In the event an Escape occurs, Supplier shall immediately take additional containment action and notify Buyer by telephone and email of Escapes of Nonconforming Product. Supplier shall fully cooperate in any investigation or containment action.

3.7.6 **Disposition of Nonconforming Product:** Supplier shall have procedures covering disposition of Nonconforming Product and Components, including review and documentation of decisions. When rework to Nonconforming Buyer product is necessary, the parties shall jointly determine the procedures for rework, retest and reevaluation of Nonconforming Product to ensure the product(s) meet specifications. Supplier shall document rework activities and provide report of rework activities to Buyer upon request.

3.7.7 **Conformity to Specification:** Buyer may reject any product that does not meet applicable specifications and will inform Supplier of the reason for any rejection.

3.7.8 **Remedies:** In the event any product has been rejected under this Agreement and Buyer has notified Supplier, or in the event Buyer has otherwise notified Supplier of a Nonconforming Product (by, e.g. quality notification, defect report, product recall, epidemic failure) Supplier shall at Buyer's direction and within the time period in the notice either repair the non-conformance; or replace the Nonconforming Products with product meeting specifications; or refund Buyer the price paid for the Nonconforming Product. Supplier will bear all costs and expenses reasonably incurred by Buyer in connection with the repair or replacement of Nonconforming Product, including without limitation, transportation, shipping, handling, storage, and related labor. If a CAPA issued in connection with

Nonconforming Product concludes the defect is Supplier caused, Supplier will, in addition to the above listed costs and expenses, be charged for documented internal and variable costs incurred by Buyer (including, without limitation, scrap, rework, analysis, engineering, containment, overtime) and Supplier will bear any damages claimed by third parties from Buyer arising from the Nonconforming Product. The remedies stated in this section are in addition to and separate and distinct from the product warranty rights and obligations under operative purchase agreements and do not modify any terms, rights or obligations under those agreements.

3.7.9 **Non-waiver:** Notwithstanding any other terms in this Quality Agreement, acceptance of product shipments, audit of Supplier's Manufacturing operations, payment or any other action by Buyer shall not constitute a waiver of Buyer's rights or remedies at law, under this Agreement or any other agreement between Supplier and Buyer (including without limitation a purchase order or Umbrella Purchasing Agreement) with respect to Nonconforming Product.

3.8 Document Controls and Changes

The Supplier shall establish a process for document control and control of changes related to product(s).

Supplier shall not modify product or processes or location of manufacturer without Buyer's written approval. Where Buyer provides such written approval Supplier shall maintain records of changes to documents related to the product(s) (e.g., DHR), which shall include a description of the change, identification of the affected documents, the signature of the approving individual(s), the approval date, and the effective date.

3.9 Purchasing Controls

Supplier shall establish and maintain controls on the purchase of components and sub-tier services to ensure conformance to specifications, including without limitation inspection of packaging, labeling, or shipping containers, and dimensional inspection or analytical testing. Supplier shall maintain documentation that clearly describes the quality requirements for components and shall require component sources to notify Supplier of any proposed changes in the components or the Manufacturing of the Components prior to making any change. Buyer may choose to evaluate Supplier's Component sources to ensure that the purchased materials meet specified purchase requirements.

3.10 Refurbished Material

Refurbished Material shall only be used in any product(s) when there is prior written approval from Buyer.

3.11 Material Rework

Only when approved by Buyer may non-conforming material rejected by Buyer may be corrected via rework provided the rework processes and steps used are evaluated, validated and documented to return the part to specification, including durability, and include a limit to the number of rework cycles a part may undergo. Rework will be documented per Supplier's process Control Plan.

3.12 Acceptance Activities

Supplier shall establish and maintain acceptance procedures with respect to the Manufacturer of the products.

3.12.1 **Supplier Receiving Acceptance:** Supplier shall have procedures for acceptance of incoming components, which shall be inspected, tested, or otherwise verified as conforming to specified Buyer's requirements. Supplier shall document acceptance or rejection of incoming components.

3.12.2 **Buyer Sourcing/Receiving Inspection:** Buyer may choose to perform source inspection at the Supplier or receiving inspection on product(s) that arrive at the Buyer receiving site. If Buyer chooses to perform source inspection at Supplier's site, Supplier shall provide Buyer reasonable access to inspect, review and audit the site(s) where the products are tested, handled, stored, distributed, designed and manufactured, including access to the product(s) and all related manufacturing information. Buyer shall provide prior notice of inspection of not less than ten (10) days, except when special circumstances warrant a shorter time, in which case the parties shall mutually agree on a time to conduct the source inspection.

3.12.3 **Final Acceptance:** Supplier shall have procedures for finished product acceptance to ensure that each production unit, lot/ batch of finished product meets Buyer's acceptance specifications. Finished product(s) shall be adequately controlled until released.

3.13 **Packaging and Labeling**

3.13.1 **Labeling:** Accompanying parts will be legible and clearly identify the part(s) being delivered.

3.13.2 **Specified labeling:** Supplier shall provide labeling where specified by Buyer and Buyer shall review and approve the label contents and placement of such labeling.

3.13.3 **Label integrity:** Packaging and labeling operations shall be controlled to ensure label integrity, proper labeling is applied, and packaging is properly conducted.

3.13.4 **Over-labeling:** Supplier shall not use over-labeling or similar corrective measures unless approved by Buyer in writing

3.13.5 **Control numbers:** Labeling shall contain product control numbers as specified by Buyer or the Supplier.

3.13.6 **Packaging:** Supplier and Buyer shall collaborate to ensure that the packaging and shipping containers for the product(s) are designed and constructed to protect the product(s) from alteration or damage during the customary conditions of processing, storage, and handling, including repackaging, and return transport for repairable Service Parts.

3.14 **Handling, Storage, Shipment**

3.14.1 **Supplier shall establish and maintain procedures for the handling, storage, and shipment of the product(s) in compliance with the following:**

i. **Handling:** Supplier shall have systems in place to ensure that mix-ups, damage, deterioration, contamination or other adverse effects do not occur during handling of the product(s).

ii. **Storage:** Supplier shall establish and maintain procedures for the control of storage areas to prevent mix-ups, damage, deterioration, contamination or other adverse effects pending distribution of the product(s).

iii. **Shipment:** Supplier shall have systems in place to control shipping of product(s) so that only product(s) approved for release are distributed. Supplier shall ensure that no obsolete,

rejected, expired or deteriorated product(s) are shipped, unless they are requested in writing to be shipped by Buyer.

iv. **Quarantined Product and Notification:** Buyer shall notify Supplier by telephone call or e-mail if quarantine of product at the Supplier is required. The Supplier shall hold all quarantined product in a secure quarantined area until authorized release by Buyer.

4. Production

Supplier shall comply with the following regarding production of the products and repair or service parts.

4.1 Process Control-Generally

Products must be manufactured at Supplier's production location verified by Buyer's selection processes, where specified by Buyer. Supplier shall have systems in place to define and maintain the manufacturing process and associated controls so that all product(s) conform to their specifications, including but not limited to:

i. Documented and approved production processes, instructions, and methods that define and control the manner of production;

ii. Monitoring and control of process parameters and component and product characteristics during production;

iii. Compliance with specified reference standards or codes;

iv. Approval of processes and process equipment; and

v. Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples

4.2 Process Monitoring and Control

4.2.1 **Business Review Meetings:** Supplier agrees to participate in Buyer held Business Review Meetings as requested with the Supplier's management team covering formal quality reviews to a documented agenda to provide heightened quality oversight and collaboration with Buyer.

4.2.2 **Process Monitoring:** Supplier shall monitor and control the manufacturing process using such tools as in-process inspection, validation and statistical process control.

4.2.2.1 **Control Plan:** When required by Buyer, the Supplier shall collaborate with Buyer to ensure a thorough understanding and identification of critical process steps, transfer function relationships, acceptable measurement capability and process capability of process input/outputs as to their impact on the CTQ parameters. The Supplier shall collaborate with Buyer to design an appropriate Control Plan. At the time of qualification, Supplier shall incorporate the foregoing into a Control Plan which will be mutually agreed upon and approved by Buyer. Supplier shall provide a measurement system analysis (e.g. gage repeatability and reproducibility, gage to part ratio), for each measurement process utilized in the Control Plan. These analyses and Control Plans will be filed with Supplier with a copy to Buyer. On an ongoing basis, Supplier will monitor production and complete inspection of each lot/batch per the Control Plan to ensure conformance. Supplier will include a Certificate of Conformance for each lot/batch based on conformance to the Control Plan.

4.2.2.2 **Process Validation:** Where the results of a process cannot be fully verified by subsequent inspection and test, processes will be validated. Process Validation plans and reports shall be documented, approved and retained by Supplier. Buyer reserves the right to review and approve Supplier's validation(s) if deemed required by Buyer. A copy shall be sent to Buyer upon request. No changes will be made to validated processes without written approval from Buyer.

4.2.2.3 **Statistical Techniques:** Supplier shall establish and maintain procedures for identifying valid statistical techniques required for establishing, controlling, and verifying the acceptability of process capability including the establishing of control limits and product characteristics in compliance with the Quality Management System requirements.

4.2.2.4 **Process Failure Modes and Effects Analysis:** When requested by Buyer, Supplier shall apply and report a Process Failure Modes And Effects Analysis (PFMEA) or equivalent risk analysis for each product as part of manufacture and process change control process.

4.2.2.5 **Part Submission Warrant (PSW):** When required by Buyer, the Supplier shall conduct and submit a PSW to ensure the long-term stability and capability of the Supplier's manufacturing process to build product that meets requirements. Buyer, in collaboration with the Supplier, will determine the required PSW elements to be performed. The Buyer will review and if deemed successful, approve the PSW submission.

4.2.2.6 In the event any of the Manufacturing process results are outside control limits or manufacturing yields decline considerably, Supplier shall inform Buyer and shall take appropriate corrective and preventive actions to rectify the situation and maintain documentation of the actions taken in compliance with the Changes and Change Notification provisions of this Agreement.

4.2.3 **Certifications:** When requested by Buyer, Supplier shall provide to Buyer certifications of specification, material or test for each item, lot/batch of product shipped – i.e. Certificates of Conformance, Certificates of Analysis, Certificates of Test.

4.2.4 **Inspection, Measurement, and Test Equipment:** Supplier shall establish a calibration program that is documented to ensure all inspection, measurement and test equipment are within their calibrated requirements. Supplier will notify Buyer immediately if calibration checks identify equipment is out of calibration and will advise Buyer of the extent of parts produced using the equipment from the time of last certified calibration. Supplier will notify Buyer in writing of any out-of-tolerance equipment that may affect the testing or Manufacturing of any Product(s) or Component. The written notification shall include identification of the affected Product(s) or Component. Buyer has the right to approve the disposition of the affected Product(s) or Component that was inspected, tested, or Manufactured with the out-of-tolerance equipment. If equipment is owned and calibrated by Buyer, the Supplier shall return equipment per Buyer request.

4.2.5 **Gage Repeatability and Reproducibility (GRR):** When requested by Buyer, Supplier shall perform and submit GRR on CTQ's.

4.3 Design

4.3.1 **Advanced Product Quality Planning (APQP):** When required by Buyer, the Supplier shall employ APQP in the development through launch of product(s) purchased by Buyer.

4.3.2 **Installation Qualification, Operational Qualification, Performance Qualification (IQ, OQ, PQ) and/or PSW:** When requested by Buyer, the Supplier shall employ IQ, OQ, PQ and/or PSW in the development through launch of product(s) purchased by Buyer.

4.3.3 **CTQ Attributes:** Buyer shall identify all CTQ attributes and/or requirements of the product(s) that require specific capability and control within the Supplier's manufacturing process. The Supplier shall measure the identified CTQ product features in an appropriate way, and upon Buyer's request, shall report such data to Buyer in an agreed upon format.

A minimum Cpk of 1.33 is required for all CTQ parameters unless parameter is 100% controlled in production.

The Supplier shall manufacture the product to conform with all requirements on the Buyer specifications.

4.3.4 **Conflicts in Requirements:** If at any time a conflict arises between design requirements and other documentation shared between parties, the parties shall notify each other of the conflict. Buyer shall resolve the conflict and communicate the resolution to Supplier.

5. Audits and Inspections

5.1 Buyer Audits

Buyer retains the right to audit Supplier Manufacturing and Quality Systems. Buyer and any third party consultant designated by Buyer shall have reasonable access to observe and inspect Supplier's facility, manufacturing and quality control processes, manufacturing and quality control records, Quality Systems, and all analytical and manufacturing documentation related to the products to ensure compliance to this Quality Agreement. Such audits may include, without limitation, the following:

5.1.1 **Pre-production Audit:** Buyer shall have the right to conduct at least one pre-production audit of Product Manufacture.

5.1.2 **Periodic Audits:** Buyer shall have the right to conduct at least one audit each contract year. Supplier shall provide Buyer reasonable access to inspect, review and audit the site(s) where the products are tested, handled, stored, distributed, designed and/or manufactured, including access to the products and all related design, product development and/or manufacturing records. Buyer shall provide prior notice of inspection of not less than thirty (30) days, except when special circumstances warrant a shorter time, such as when patient safety is a concern, in which case the parties shall mutually agree on a time for prior notice. Supplier shall not unreasonably reject proposed audit schedules. Buyer reserves the right to audit Sub-tier Suppliers under similar circumstances. Supplier shall cooperate with and support such audits and shall use reasonable efforts to maintain contractual rights to such audits.

5.1.3 **For-Cause Audits:** For-cause audits shall be for the purpose of investigating a potential quality problem or significant complaint regarding a product potentially attributable to manufacturing or other operations at Supplier. If Buyer believes a for-cause audit is needed, Buyer will notify Supplier of the request and reason for the for-cause audit. Supplier shall not unreasonably reject a request for a for-cause audit. For-cause audits shall be scheduled as quickly as possible, taking into consideration the urgency of the request, but in no event later than five (5) working days from the request date. Buyer reserves the right to audit Sub-tier Suppliers under similar circumstances. Supplier shall cooperate with and support such audits and shall use reasonable efforts to maintain contractual rights to such audits.

5.1.4 **Unannounced Audits:** Buyer, Notified Body or relevant Competent Authority assessing Buyer's product, shall have the right to access Supplier technical documentation and Sub-tier Supplier

records for material and components supplied to Buyer, if required. Supplier and Sub-tier Supplier shall provide Notified Body and Competent Authorities access to the premises of their manufacturing facilities if required.

5.1.5 **Procedures While On Site:** Buyer's employees and/or representatives including consultants who inspect Supplier facilities shall comply with all Supplier safety and supplier policies and procedures that are communicated to the persons on site.

5.1.6 **Audit Closeout:** On completion of the audit, an audit finding review will be performed with Supplier. Where there are audit findings, Supplier shall provide a response to those findings and Buyer and Supplier will discuss the findings and responses which may include corrective actions. Buyer shall provide a written report of all findings and observations to Supplier within thirty (30) days of the last day of the audit. Within thirty (30) days of the audit report receipt, Supplier shall provide a written response to all findings that details corrections and corrective action to be implemented. Supplier shall follow up to ensure that all corrections and corrective actions are implemented.

5.2 Internal Audits by Supplier

Supplier shall conduct internal audits compliant with its Quality System and this Agreement. Upon Buyer's request, Supplier shall provide Buyer with the results and conclusions of the audits.

5.3 Management of Sub-tier Suppliers

Supplier shall implement, maintain and ensure oversight and monitoring of Supplier's Sub-tier Suppliers following a documented, risk-based approach that complies with Supplier's own internal procedures and Quality Management System and Buyer's Specifications, including without limitation, audit rights of the Sub-Tier Supplier. Buyer may elect to provide input into this risk assessment of Supplier's Sub-tier Suppliers and may require Supplier to escalate the risk and consequently the oversight as applicable for the product. Buyer may determine in cooperation with Supplier which Sub-tier Suppliers are to be reviewed during Business Review Meetings. Upon request by Buyer, Supplier shall identify for Buyer whether Supplier and/or Buyer has audit rights under a contract with a Sub-Tier Supplier. Supplier shall cooperate with and support audits of its Sub-Tier Suppliers by Buyer and shall use reasonable efforts to maintain contractual rights to such audits.

5.4 Regulatory Audits and Inspections

Supplier agrees the FDA and other Authorities shall have access to and the right to inspect or audit any pertinent product(s) design, manufacturing, or quality processes, and associated documentation or records.

5.5 Notification

5.5.1 **Third Party Audits:** Supplier shall promptly notify Buyer when an Authority inspection of its facilities (or an inspection by third parties in accordance with FDA regulations or inspection by another governmental authority such as a Notified Body) is expected and/or underway with sufficient notice to allow Buyer to attend the audit or inspection. Notification shall include the name of the regulatory Authority or test lab/agency, dates, and the scope of activity. Post audit notification shall include ongoing certification status, and the audit or inspection results, including any FDA Form 483 observations, ISO nonconformance, or test lab/agency variance notices.

5.5.2 **Identified Issues:** If issues are identified during any inspection or audit which are related to or could have impact on the product quality, performance or availability, Supplier shall notify Buyer by email or phone within 24 hours of the event with written follow-up within three (3) business days.

5.5.3 **Regulatory Correspondence:** Supplier shall promptly provide Buyer with copies of all regulatory correspondence, any correspondence with the FDA or any other Authority related to processes, components or equipment which are the same or similar to those used in the Manufacture of the Products.

5.5.4 **Regulatory Commitments:** Supplier shall secure Buyer's written agreement prior to making any commitment to a regulatory agency regarding the Product. Buyer shall be provided with draft responses to regulatory observations that involve the product and its manufacture prior to submission to any regulatory Authority and Supplier shall permit Buyer's input into responses and corrective actions. Supplier shall retain the final authority and responsibility for the content of the responses to the Authority related to a product.

6. Changes and Change Notification

6.1 Changes by Buyer

Specifications may be revised by Buyer. Such revisions may require additional qualification/validation. Buyer shall notify Supplier of all relevant specification revisions. Supplier will respond to Buyer within ten (10) days of receipt of notification with the following communication as applicable: a) supplier's lead time for implementation of changes, b) impact to tooling, testing or other non-recurring engineering changes, c) changes on lead time of product, and d) any other impact to product, including impact to quality.

6.2 Changes by Supplier

Supplier will not change, substitute or modify products, nor make any changes that may affect the specifications. Any changes proposed or intended to be made by Supplier, or changes by Sub-tier Suppliers, must be submitted to Buyer in writing for review and approval prior to making any such changes on the Buyer specified format (See 6.3 below for changes requiring submission to Buyer). When Supplier submits changes for Buyer's approval, the information submitted must include a complete description of the change, including at a minimum the Buyer part number affected, serial numbers of product to be affected, proposed date of implementation of change, reason and specific details of the change and be documented in the appropriate form provided by Buyer. Working jointly with Buyer, Supplier must determine the effect the change will have on the characteristics of the product and where required by Buyer complete a Product Submission Warrant (PSW). Upon request, the Supplier shall submit samples of the proposed product for evaluation and approval by Buyer. Supplier shall not implement any such change without Buyer's prior written consent. Product affected by such changes may not be shipped by Supplier to Buyer or its customers until Supplier has received written approval from Buyer of the change.

6.3 Change/Approval

Buyer shall review and approve changes that may affect the product(s), including, without limitation:

All process changes including changes related to:

- Process method or technology

- Control Plan
- Product performance issue
- Process Validation
- Process deviation
- Test Software which affects the product (e.g. programming MAC address change)
- Process Failure Modes & Effects Analysis (PFMEA)
- Product final acceptance test issue
- Supplier Manufacturing site transfers
- Sub-Tier Supplier changes
- Transportation method

Material:

- Changes to materials and/or Components (BOM)
- Change in a supplier of a material or Component

Change in Component or Product requiring:

- Updated Component Specification
- Updated Product Specification
- New or alternate Sub-Tier Supplier

Change in Supplier:

- Name
- Address

Change in Product design:

- Product
- Labeling
- Packaging

Change to Product part number

Change to Manufacturing, test, or inspection equipment:

- New equipment

- Equipment Qualification or Validation
- Change from manual to automated process
- Disposition of Product affected by out of tolerance equipment

Facility Changes:

- Move of Manufacturing equipment within the same Manufacturing facility
- Facility to facility transfer of Manufacturing processes or technology.
- Altering environment specs or conditions in areas used for Manufacturing, storage, or test (i.e. microbial/endotoxin/particulate monitor)

In-process and final acceptance test changes related to:

- Test specification
- Test acceptance requirements
- Test application Validation
- Products reviewed by Supplier MRB for "Use As Is" disposition
- Outgoing Inspection Plan
- Reduction in either 100% testing or sampling plans

6.4 **Component Change/Approval**

Supplier shall ensure that entities that supply Components follow the same procedure as required of Supplier in the preceding section.

6.5 **Notification of Site/Line Change**

Additionally, Supplier shall give Buyer at least twelve months' notice of any intent to shut down or move a manufacturing line on which the products are produced.

7. Record Production and Retention

7.1 **Creation and Maintenance**
Supplier shall create and maintain records for the activities for which it is responsible under this Quality Agreement in compliance with its Quality Management System requirements.

7.1.1 **DMR**: Buyer controls and has ownership of the DMR, but it may reside with Supplier for a period of time as specified in Section 7.7 (Retention), after which time it shall be transferred to Buyer.

7.1.2 **DHR:** Supplier shall create and maintain a DHR for each product that demonstrates that such product was manufactured in accordance with the DMR and the Quality Management System requirements. Supplier shall provide copies of the DHR to Buyer upon request. Buyer retains ownership of the DHR.

7.1.3 **DHF:** Buyer shall own the Product's DHF, but it may reside with Supplier for a period of time as specified in Section 7.7 (Retention), after which time it shall be transferred to Buyer.

7.2 Ownership

All such records and other documents required to be maintained pursuant to this Quality Agreement and/or documents provided by Buyer shall be the sole property of Buyer.

7.3 Location of Records/Record Inspection

Records and other documents required to be maintained pursuant to this Agreement shall be available at reasonable times for inspection, examination and copying by or on behalf of Buyer, or for inspection by third parties, including Agencies, for so long as any of them are in Supplier's possession.

7.4 Copies

Upon Buyer's request, Supplier shall promptly provide Buyer with copies of records and other documents required to be maintained pursuant to this Agreement.

7.5 Original Records

Supplier shall not transfer, deliver or otherwise provide to any third parties original records or other documents required to be maintained pursuant to this Agreement without prior written consent of Buyer.

7.6 Third Party Access

Supplier shall not transfer, deliver or otherwise provide to any third parties, except as required by law, regulation, or administrative or judicial order, copies of records or other documents. If Supplier is so required to disclose such copies of such records or other documents, Supplier shall immediately notify Buyer of any such request to give Buyer the opportunity to protect its interests in such records and documents.

7.7 Retention

Supplier shall keep and maintain records for at least five (5) years or the lifetime of the product, whichever is greater. After this period has elapsed, Supplier shall notify Buyer prior to destroying any records and provide a copy of such records upon Buyer's request. At any time upon written request, and expiration of this Quality Agreement, Supplier shall return all records to Buyer. In the event that the Supplier closes or sells the business, Supplier shall transfer all records to Buyer.

8. Term

This Agreement and the quality requirements set forth in this Agreement are effective as of the Effective Date and shall remain in full force and effect for as long as Supplier provides products to Buyer. This Agreement may will terminate when the applicable purchasing agreement terminates, provided that in no case will this Agreement be terminated while Supplier is providing products to Buyer.

9. Survival

All provisions which are continuing in nature, including but not limited to Sections 2.6, 2.7, 4.1, 4.3, 4.4, 4.5, and 6 shall survive expiration of this Agreement.

10. No Amendment; Entireties; Governing Law

This Agreement may not be amended or modified except by a written instrument specifically referring to this Agreement signed by authorized representatives of both Supplier and Buyer, provided however, the parties may revise or amend Appendix A to this Agreement at any time during the term by having both parties sign and date the revision to the Appendix and specify the effective date of the revision. Supplier shall not assign its rights or delegate performance of its obligations under this Agreement without the express prior written approval of the Buyer entity signing this Agreement (or its successor). This Agreement shall be binding on any successors and permitted assigns of Supplier. This Agreement contains the entire understanding of the parties with respect to the subject matter of the Agreement and supersedes all prior or contemporaneous agreements or understandings. This Agreement will be deemed to be made and, in all respects, will be interpreted, construed and governed by and in accordance with the laws as described in the applicable purchasing agreement without regard to conflicts of laws principles. If no such laws are described, the laws of Massachusetts, USA state shall control. The United Nations Conventions on Contracts for the international Sale of Goods (the Vienna Sales Convention) is not applicable to this Agreement.

(Buyer Name)

Signature: _____

Name: _____

Title: _____

Date: _____

(Supplier Name)

Signature: _____

Name: _____

Title: _____

Date: _____

610 Presidential Dr, Ste 110 Richardson, TX 75081

Rev	Summary of Changes and Effectivity Date	Effective Date	Author
01	Initial Release		

610 Presidential Dr, Ste 110 Richardson, TX 75081

APPENDIX

Note: To be used for specification/ requirements documents for the items being purchased

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