1.0 Administrative Elements

1.1 Scope

This agreement defines the Quality Agreement between the parties identified below. It defines the commitment both parties make to ensure that their respective products and services satisfy the quality and regulatory requirements called out in this agreement. Both parties agree to cooperate in the success of this agreement.

This agreement does not define the forecasting, ordering, delivery, or pricing requirements for either party. This agreement does define the specifications for the products or services covered.

1.2 Parties to the Agreement

This Quality Agreement is executed between

_____(Supplier Name) with business address at

_____(address), hereafter referred to as _____ (Supplier) and **Acuderm, Inc.** with business address at

6555 Powerline Rd Suite 114, Fort Lauderdale, FL 33309, hereafter referred to as (Customer). (Supplier) agrees to provide the goods or services defined below in full conformance with the requirements of this agreement.

1.3 Definitions, Abbreviations, and Acronyms

The following terms are included in this agreement:

CAPA – Corrective and Preventive Action

Corrective Action – Action to eliminate the cause of a detected nonconformity or other undesirable situation

Product – Product is the output of a process and includes, but is not limited to, goods, services, software, documentation, and consulting.

QMS – Quality Management System

Supplier – The Supplier delivers product to the Customer. The term Supplier includes, but is not limited to, contractors, consultants, services and third party suppliers.

1.4 Products and Services Covered by This Agreement

This agreement pertains to the products listed in Appendix A.

1.5 Use of Third Parties

1.5.1 Directed Procurement

For the purposes of this agreement, the Supplier does not have to qualify their Third Party Suppliers. However, if the Supplier chooses to qualify their Third Party Supplier, it should be listed in Appendix A. If the Third Party Supplier carries ISO Certification or other QMS certifications, they can list it in Appendix A.

Note: Typical examples include an electrical transformer manufactured to your specifications that carries a UL mark or a previously validated sterilization process.

When used on, applied to, or incorporated into the product provided to the Customer, the Supplier shall purchase the listed goods or services from the designated Third Party Supplier. The Supplier shall provide the Customer if requested, with monthly performance reports on these Third Party Suppliers that includes the number of purchase order lines placed with the Third Party Supplier, the percentage of shipments received late, and the percentage of shipments rejected at receiving acceptance.

1.5.2 Supplier Selected

If the Supplier uses a Third Party Supplier (See Appendix A), other than directed procurement, to manufacture, package, label, test, or release product provided to the Customer, Appendix A should list the role of that supplier.

1.6 Term of Agreement

This Agreement shall become effective and binding upon the date of the final signature and shall remain in effect until 2 years after the last delivery of any product by the Supplier to the Customer unless the Customer specifically requests an extension of the Agreement. Either party may terminate this Agreement by giving 6 months written notice to the other party.

1.7 Assignment

Neither party shall have the right to assign any or all of its rights or obligations under this agreement without the other party's prior written consent, which shall not unreasonably be withheld. The foregoing notwithstanding, prior written consent shall not be required in connection with a merger, consolidation, or a sale of all or substantially all of party's assets to a third

party, except if such merger, consolidation, or sale is with a competitor of the other party.

2.0 Compliance

2.1 Specifications

The Customer shall define the specifications for the product the Supplier provides. This could take many forms including drawings, reference to commercial specifications, identify of brand names, and standards. The specifications may be paper documents, electronic documents, or other appropriate media.

The Supplier undertakes to deliver product in full conformance to the agreed specifications. (See Appendix A)

2.2 Specification Changes

Changes to specifications are made by mutual written agreement between the Supplier and the Customer. In addition to agreement of the change, the Supplier and Customer will determine the effective date of the change. No changes to materials, fit, form, function, composition, color, etc. shall be made without prior written authorization of Customer.

When the specifications include references to brand names, the Supplier and Customer will mutually agree in writing on the implementation of any changes made in the brand name product. For accepted changes, the Supplier and Customer will work together to develop a plan to implement the changes.

2.3 Activity by Regulators, Notified Bodies, or Certification Bodies

It is Acuderm Inc's right to perform audits to its suppliers and ask for any

previous external audits reports. This includes but is not limited to the Food and Drug Administration, the Environmental Protection Agency, and the Occupational Safety and Health Administration. It also includes ISO 13485:2016, TGA, ANVISA, MHLW/PMD, FDA 21 CFR 820.50, and corresponding State Agencies.

Upon the Customer's request, the Supplier shall disclose the results of any inspections or audits and the associated cause and corrective action as they relate directly to the Customer's products.

The Supplier shall promptly notify the Customer in writing of any inspection or audit findings that affect the safety, effectiveness, conformity, or availability of product the Supplier provides to the Customer.

3.0 Providing Product or Service

3.1 Work Environment

If environmental conditions could reasonably be expected to have an adverse effect on product quality, the Supplier shall establish and maintain procedures, including maintenance, adjustment, and inspection to adequately control these environmental conditions.

The Supplier shall keep records of these activities and make them available to the Customer upon request.

3.2 Personnel

If contact between personnel and the product could reasonably be expected to have an adverse effect on product quality, the Supplier shall establish and maintain requirements for the health, cleanliness, personal practices, and clothing of personnel to adequately control this contact. The Supplier shall keep records of these activities and make them available to the Customer upon request.

3.3 Equipment

The Supplier shall ensure that all equipment used in the manufacturing process for the product is appropriately designed, constructed, placed, and installed.

The Supplier shall establish and maintain schedules for the adjustment, cleaning, and other maintenance of equipment to ensure that manufacturing specifications are met.

The Supplier shall keep records of these activities and make them available to the Customer upon request.

3.4 Automated Processes

If the Supplier uses computers, software, or other automated methods as part of the production process, the Supplier shall validate the computer software for its intended use. The validation process shall create a validation protocol (describing the planned activities) and a validation report (documenting the outcome of the planned activities). All software changes shall be similarly validated prior to use.

The Supplier shall keep records of these activities and make them available to the Customer upon request.

3.5 Monitoring and Measuring Equipment

The Supplier shall ensure that all monitoring and measuring equipment used in the manufacturing process for product is suitable for its intended purposes and is

capable of producing valid results. Suitability includes limits for accuracy and precision.

The Supplier shall establish and maintain schedules for the calibration, adjustment, cleaning, and other maintenance of equipment to ensure that manufacturing specifications are met.
Calibration standards used for monitoring and measuring equipment shall be traceable to national or international standards.

3.6 Packaging Operations

The Supplier will pack and package the product using the agreed methods or best practices to protect the product from deterioration or damage during processing, storage, handling, and shipment.

4.0 Documentation and Records

4.1 Record Retention

Records required by the agreed upon quality system will be maintained for a period of lifetime of the device plus 5 years to a 15 years minimum.

5.0 Storage and Shipment

5.1 Storage

The Supplier shall establish and maintain procedures to control storage areas and stock rooms to prevent mix-ups, damage, deterioration, contamination, or other adverse effects.

The Supplier shall ensure that all products are stored to facilitate proper stock rotation and that product is retrieved from stock using First In, First Out (FIFO) methodology.

5.2 Shipment

The Supplier shall ship products to the Customer using agreed shipping methods to prevent the damage or deterioration of the product.

6.0 Change Control

6.1 Change Requests

If the Supplier requests to change a document, specification, drawing, *etc*. under the Customer's control, the Supplier shall document the request including the specific change, the reason for the change, the benefit derived from approving the request, the loss incurred from disapproving the request, and the anticipated lead-time before the change is reflected in the product. No changes to materials, fit, form, function, composition, color, etc. shall be made without prior written authorization of Customer.

6.2 Deviations

If the Supplier needs to deviate from a document, specification, drawing, *etc*. under the Customer's control, the Supplier shall document the deviation request including the specific deviation, the reason for the deviation, and the period (time, lots, *etc*.) the deviation will be in effect. This deviation must be communicated to the Customer in writing.

6.3 Other Changes

The Supplier shall promptly notify the Customer of changes deemed significant by the supplier, other than those documented above, in the product or service so the Customer may determine whether the changes may affect the quality of a finished device. No changes to materials, fit, form, function, composition, color, etc. shall be made without prior written authorization of Customer. For accepted changes, the Supplier and Customer will work together to develop a plan to implement the changes

7.0 Nonconformance, CAPA, and Complaints

7.1 Disposition of Non-conforming Material

The Supplier shall segregate, investigate, and disposition all nonconforming material. The Supplier is authorized to make rework and scrap dispositions without Customer Authorization. Concession or repair dispositions require the Customer's written authorization.

If the Supplier requests authorization for a repair or concession disposition, the Supplier shall document the disposition request including the inspection or test conducted, the actual results, and, if applicable, the proposed repair.

7.2 Corrective Action

7.2.1 Supplier Initiated Corrective Action

The Supplier shall initiate corrective action for all detected nonconforming material regardless of disposition. Corrective Action shall include the following steps:

1. Determining the cause(s) of nonconformity
2. Evaluate the need for action to ensure the nonconformity doesn't recur
3. Determine the action needed to prevent recurrence
4. Implement the action needed to prevent recurrence
5. Review the effectiveness of the corrective action

The Supplier shall keep records of these activities and make them available to the Customer upon request.

Customer Initiated Corrective Action

The Customer may initiate corrective action for the Supplier when the Customer identifies a nonconformity after receipt of the Supplier's product. The Supplier shall initiate corrective action upon receipt of the Customer's initiation. The Supplier's Corrective Action shall include the following steps:

1. Determining the cause(s) of nonconformity
2. Evaluate the need for action to ensure the nonconformity doesn't recur
3. Determine the action needed to prevent recurrence
4. Implement the action needed to prevent recurrence
5. Review the effectiveness of the corrective action

The Supplier shall report the results of the corrective action to the Customer within 15 working days of initiation. When the Corrective Action is not completed within 15 working days, the Supplier shall provide a status report every 5 working days until the corrective action is completed. The Supplier shall keep records of these activities and make them available to the Customer upon request.

7.3 Complaints

7.3.1 Supplier Received Complaints

If the Supplier receives a complaint related to the product, or any similar product, the Supplier provides to the Customer, the Supplier shall promptly notify the Customer.

The Customer will enter the complaint into the Customer's Complaint Management System and review and evaluate the complaint. The Customer will notify the Supplier of the result of the review and evaluation.

If the Customer requires the Supplier's assistance in the investigation, the Customer will follow the Customer Initiated Corrective Action described above.

7.3.2 Customer Received Complaints

If the Customer receives a complaint related to the product the Customer supplies, the Customer will enter the complaint into the Customer's Complaint Management System and review and evaluate the complaint.

If the Customer requires the Supplier's assistance in the investigation, the Customer will follow the Customer Initiated Corrective Action described above.

8.0 Audits

8.1 Customer Audits of Supplier Facilities

The Supplier will consider requests from the Customer, or its authorized representative, to perform audits of the Supplier's facilities, systems, documentation, and other requirements related to this agreement.

Audits shall be conducted on mutually agreed dates and times.

The Supplier and Customer will agree upon methods to protect intellectual property such as confidentiality agreements, non-disclosure agreements, etc.

The Supplier will be provided with a Supplier Assessment form by the Customer and will be used for monitoring and re-evaluation of its suppliers. Supplier performance in meeting requirements for the purchased product will be monitored through various methods, (i.e., receiving inspection, NCR's, assessment form, etc.). The results of the monitoring shall provide an input into the supplier re-evaluation process.

8.2 Customer Audit Findings

When conducting audits at the Supplier's location, the Customer will issue an Audit Report within five working days of the audit's conclusion.

The Supplier shall issue a plan to determine the correction, cause, and corrective action for each finding within thirty days of the Audit Report's issue date.

8.3 Auditing Third Party Suppliers

The Supplier will consider requests from the Customer, or its authorized representative, to perform audits of the Third Party Supplier's facilities, systems, documentation, and other requirements related to this agreement.

Audits shall be conducted on mutually agreed dates and times.

The Supplier, Customer, and Third Party Supplier will agree upon methods to protect intellectual property such as confidential agreements, non-disclosure agreements, etc.

8.4 Unannounced Audits by Notified Audits

The notified body shall randomly perform unannounced audits on the Customer facilities and, where appropriate, the Supplier shall allow the Notified Bodies to perform unannounced audits of their facilities and/or Third Party Supplier's facilities.

SUPPLIER: _____	**CUSTOMER:** Acuderm, Inc.
Signature: _____	Signature: _____
Printed Name: _____	Printed Name: _____
Title: _____	Title: _____
Date: _____	Date: _____
Phone: _____	Phone: _____
Fax: _____	Fax: _____
Email: _____	Email: _____

Appendix A

Customer's Part Number	Rev.	Description	Supplier's Part Number (if applicable)

Third Party Supplier	Product or Service	QMS Applied (ISO Cert)