

QUALITY AGREEMENT

Between

And

**C&G Laboratories
1410 Southtown Drive
Granbury, Texas 76048**

Issue date:

Revision History		
Amendment	Detail of Change	Date
n/a	Original issue	

QUALITY AGREEMENT APPROVALS:

(Quality Agreements between I sites require the approval of the site manager, QA and RA)

I Austin

Quality Assurance

Name

Title

Signature

Date

Regulatory Affairs

Name

Title

Signature

Date

Site / Plant Manager

Name

Title

Signature

Date

I LifeSciences Corporate Office

Corporate QA (if required)

N/A

Name

N/A

Title

N/A

Signature

N/A

Date

CG Labs (Granbury, Texas)

Quality Assurance

Name

Title

Signature

Date

Regulatory Affairs

Name

Title

Signature

Date

Site / Plant Manager

Name

Title

Signature

Date

1. PURPOSE

The purpose of the Quality Agreement is to clearly outline key responsibilities for communication, controls, and quality assurance measures that must be established for both I LifeSciences Austin and C&G Laboratories located at 1410 SouthTown Dr. Granbury Texas 76048. This Quality Agreement will ensure that products are manufactured according to agreed-upon specifications and Quality System requirements.

C&G Labs is responsible for cleaning/ decontamination devices manufactured by I LifeSciences and providing consultation services in matter of sterilization and cleaning of medical devices.

This Quality Agreement is entered into and made effective upon the date of its signature by all approvers.

Approval of this Quality Agreement will ensure that products are provided according to specifications and that products comply with applicable FDA Quality System Regulations, cGMPs, EN ISO 13485, the Canadian Medical Device Requirements (CMDR), the Medical Directive (93/42/EEC plus amendments), any other applicable regulations, product specifications and company policies and procedures as applicable.

2. SCOPE

This agreement is applicable to all products that are cleaned / decontaminated at C&G Labs. C&G Labs Granbury facility is responsible for cleaning / decontamination of products that are returned from I customers (Surgeons, Hospitals, Surgery Centers, Distributors, and Global Distribution Centers etc.) Or from one of the I's facility.

3. QUALITY AGREEMENT REVIEW AND MAINTENANCE

It is the responsibility of the site Manager of QA (or delegate) to ensure that this agreement is reviewed annually. Modifications shall be made as required following the current change control procedure at the Site and approved by the same functions that signed the original agreement. Management at both facilities shall communicate any information in case of discrepancy, issues, changes related to the requirements described hereafter.

4. RESPONSIBILITIES

The Manager of Quality Assurance for I LifeSciences Austin and the designated representative(s) at C&G Labs at Texas site is responsible for ensuring that this Quality Agreement is properly executed.

5. QA CONTACTS

I Austin	C&G Labs
Vishwas Sharma	Briana Monroe
Sr Manager, Supplier Quality Management	Quality Assurance Manager
+1-(512)-852-3945	+1-817-279-1945
vishwas.sharma@llife.com	bmonroe@cg-labs.com

6. DEFINITIONS

I site - refers to the I LifeSciences site who is the design control owner.

Supplier - refers C&G laboratories Texas, that is providing the finished products

Nonconforming product - refers to a product that does not fulfil of a specified requirement.

Complaint - refers to any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, efficiency, or performance of a device after its release for distribution.

Recall - refers to the removal or correction of a marketed product that the Competent Authority considers to be non-conforming with standards and against which the agency could initiate actions.

7. MANAGEMENT RESPONSIBILITY

The Vice President/Quality Leader at Supplier and I are responsible for quality planning and assuring that resources are dedicated to achieve requirements of regulatory agencies and customers.

8. QUALITY AUDITS

Both parties are responsible for having an internal and supplier audit program in place. Based on the existing EU Medical Device Directive (93/42/EEC, as amended), Notified Bodies have the authority to perform unannounced audits. To verify day-to-day compliance to legal requirements, I's Notified Bodies may determine it is necessary to visit the site of a critical component or finished device manufacturer without prior notice. If you choose to deny access to a Notified Body's audit team, please notify I immediately. Your cooperation, if an unannounced visit should occur, is sincerely appreciated. Supplier shall allow the I Notified Body and the Competent Authority of I to examine technical documentation held by C&G labs site for products specifically supplied to I.

9. QUALITY SYSTEM /REGULATORY COMPLIANCE

C&G labs shall notify I within twenty-four (24) hours of receipt of contact from the FDA, ISO Notified Body, or any other regulatory agency if such entity contacts C&G labs to investigate or inspect its facilities with respect to the Products or manufacturing records of the Products provided to I and notify I of any applicable findings or corrective actions related to their Product. C&G labs will immediately notify I of any regulatory action taken against C&G labs that would affect product availability or bring into question the quality and safety of the Products sourced by I.

I shall notify C&G labs within twenty-four (24) hours of any FDA, ISO or any other regulatory agency audit of I that is related to Products cleaned at C&G labs site or services provided by C&G labs and notify C&G labs of any applicable findings or corrective actions related to the Products. In addition, where a response or corrective action and preventive action are required, I will submit a response to C&G labs for review prior to submission, as applicable.

10. Record Retention

C&G labs shall retain all documentation generated during the manufacturing process as required by I's Standard Operating Procedures (hereinafter "SOPs") and based on the expected life of the device, but no less than five (5) years from the date of release of the device for commercial distribution. I shall retain distribution documentation in accordance with I's SOPs.

11. AGREEMENT MAINTENANCE

This Quality Agreement may be reviewed as mutually agreed upon by the Parties. No amendment, modification or alteration to this Quality Agreement shall bind either Party unless made in writing and approved by both Parties.

This Quality Agreement shall commence on the Effective Date and shall remain in effect for as long as C&G Labs supplies product to I LifeSciences.

QUALITY AGREEMENT REQUIREMENTS

Duties	I Austin (Site)	C&G Labs (Supplier)	Comments
Regulatory and Compliance			
<ul style="list-style-type: none"> Follow applicable regulations and European Good Manufacturing Practices including Directive 93/42/EEC, as amended, and the U.S. FDA 21 CFR 820 	X	X	
<ul style="list-style-type: none"> Any submission requirements (FDA, Notified Body, Health Canada, Government laws) 	X		
<ul style="list-style-type: none"> Technical Files 	X		I will maintain the product technical files
<ul style="list-style-type: none"> Product recall investigation 	X	X	This will be led by the Site; however, Supplier will provide support as requested.
<ul style="list-style-type: none"> Product recall reporting 	X	X	This will be led by the Site; however, Supplier will provide support as requested
<ul style="list-style-type: none"> Establishment registration and medical device listing with FDA and availability of registration registered form. 	X	X	Both parties are responsible for maintaining Establishment registration and medical device listing with FDA.
<ul style="list-style-type: none"> Facility registration with ISO Notified Body. 	X	X	Supplier to be certified per ISO 13485 and ISO 9001:2008, at minimum
<ul style="list-style-type: none"> Notify I of key organizational and/or key personnel changes 		X	For example, moving to new facility, change in quality or operations management, acquisition or merger
<ul style="list-style-type: none"> Other Regulatory Requirements, e.g. radiation compliance, risk management file management 			N/A
Audit - Internal			
<ul style="list-style-type: none"> Maintain internal Good Manufacturing Practices audit program 		X	
<ul style="list-style-type: none"> Identify and implement corrective actions to internal audits 		X	
<ul style="list-style-type: none"> Review of Audit report 		X	Significant findings that may affect product safety or efficacy shall be communicated to the Site, by the Supplier's QA Director, along with the plans for corrective action.
Audit - External			

Duties	I Austin (Site)	C&G Labs (Supplier)	Comments
<ul style="list-style-type: none"> Review of a Notified Body or FDA Audit report 		X	Significant findings which may affect product safety or efficacy shall be communicated to the Site by Supplier QA Director or designee along with the plans for corrective action.
Design Control			
<ul style="list-style-type: none"> Maintenance and storage of DHF 	X		
<ul style="list-style-type: none"> Design activities including Risk Management 	X	X	Supplier to maintain risk management file for the activities performed at their site. Supplier should perform risk management activities as per their internal procedures.
<ul style="list-style-type: none"> Review of Design Changes 	X	X	Formal supplier approval is not necessary; however, any issues with the Supplier's ability to meet design changes shall be communicated to the Site. Any change to products specification processed at the supplier site will be communicated to the supplier by I immediately upon I's approval.
Change Control / Document control			
<ul style="list-style-type: none"> Review and approval of Engineering Change pertaining to products defined in the scope section of this document 	X		I will inform C&G of Engineering changes pertaining to products defined in the scope of this quality agreement, if it impacts any cleaning activities done at their site.
<ul style="list-style-type: none"> Review and approve Device Master Records 	X		
<ul style="list-style-type: none"> Review and approval of Supplier Quality System documents 		X	Notification to Site if quality system changes affect products in scope of this Quality Agreement including new certificates
<ul style="list-style-type: none"> Review and approve Device History Records 	X		Record UDI information for each finished device.
<ul style="list-style-type: none"> Notify I of all changes to facility, process, equipment, test methods, quality systems and specifications that impact Product identity, safety, purity, stability, regulatory status or 		X	Supplier shall notify I of any change to manufacturing process that may affect I products this includes changes to any cleaning/

Duties	I Austin (Site)	C&G Labs (Supplier)	Comments
validation/qualification. Change control process should account for changes including, but not limited to facility, process, test methods, functionality, quality specifications and approved vendor, raw materials, component specifications.			decontamination processes, chemicals etc.
<ul style="list-style-type: none"> Document all required process and testing steps at the time such process or testing step is executed, e.g. cleaning and packaging validation. 	X	X	
Product & Process Environment (If Applicable)			
<ul style="list-style-type: none"> Manufacture, package, ship, store, and test the Product and materials in an environment meeting the applicable GMP regulations, which is designed, constructed and maintained in a manner that a) permits the operation therein to be performed under clean, sanitary and orderly conditions, b) prevents the contamination of the Product and the addition of extraneous material to the Product. 		X	
<ul style="list-style-type: none"> Refrain from activity that could adversely affect the Product. 	X	X	
<ul style="list-style-type: none"> If applicable, establish and maintain a program for environmental monitoring including tracking and trending processes. 		X	
<ul style="list-style-type: none"> Buildings and facilities used in the manufacture of the Product shall be designed, constructed and maintained to facilitate cleaning, maintenance and operations and to ensure orderly placement of equipment and materials to prevent mix-ups and contamination as appropriate to the type and stage of manufacture. 		X	
<ul style="list-style-type: none"> Maintain and document an adequate pest control program 	X	X	

Duties	I Austin (Site)	C&G Labs (Supplier)	Comments
<ul style="list-style-type: none"> Work Environment 		X	Supplier shall establish documented requirements for health, cleanliness, and clothing for personnel involved in the manufacture of the Product
Sterilization (If applicable)			
<ul style="list-style-type: none"> Validation/ revalidation 	X	X	C&G labs will be responsible for validation/ revalidation of Cleaning, sterilization activities that C&G performs for I products.
Product Release			
<ul style="list-style-type: none"> Retains 	X		
<ul style="list-style-type: none"> Finished Goods Shipment 		X	Should be done as per supplier Internal packaging / shipping procedures.
Nonconforming Product & Out of Specification Tests			
<ul style="list-style-type: none"> Have appropriate procedures for identification, investigation, reporting, tracking, trending and closure of deviations. 	X	X	All non-conformances are to be handled by I and the supplier as per their Quality System.
<ul style="list-style-type: none"> Segregation, evaluation, and disposition of non-conforming product 	X	X	All non-conformances are to be handled by supplier and I under their Quality System.
<ul style="list-style-type: none"> Approval of concession to use out-of-specification material 	X	X	Notify I within 3 business days of any deviation or out-of-specification situation affecting the quality of the Product.
<ul style="list-style-type: none"> Trending of nonconforming material 	X	X	As per procedure
<ul style="list-style-type: none"> Provide investigation documentations to I upon request 		X	
<ul style="list-style-type: none"> Complete investigations within thirty (30) days of commencement. Supplier shall notify I in writing if investigations will extend beyond the original thirty (30) days. 	X	X	
<ul style="list-style-type: none"> Complete corrective action commitments resulting from investigations or complaints within the planned timeframe. 	X	X	

Duties	I Austin (Site)	C&G Labs (Supplier)	Comments
<ul style="list-style-type: none"> Have a rework procedure for Product requiring rework describing the rationale and justification for the rework processes. Rework is a manufacturing step involving a technique or technology that is not a part of the approved process sequence. 		X	Rework or Retesting procedures require review and approval by I
<ul style="list-style-type: none"> For any product that is reworked, record of rework is to be provided to Site. 		X	
<ul style="list-style-type: none"> Quarantine Procedure 	X	X	I and Supplier are responsible for having a quarantine procedure and work flows as applicable during their control of the product.
Product Complaints			
<ul style="list-style-type: none"> Maintained finished device complaint files 	X		
<ul style="list-style-type: none"> Testing or evaluation of complaint samples 	X	X	Customer complaint returns may be accompanied with a Supplier Corrective Action Request (SCAR)
<ul style="list-style-type: none"> Investigation of complaint root cause 	X	X	Site may need to be involved when design issues are encountered
<ul style="list-style-type: none"> Implementation and verification of Corrective Action Taken 	X	X	Site may need to be involved when design issues are encountered
<ul style="list-style-type: none"> Complaint trending and reporting 	X		
<ul style="list-style-type: none"> Submissions of MDR/MDV/Canadian/other Mandatory Reporting 	X		
Qualification and Training			
<ul style="list-style-type: none"> Provide sufficient training to meet obligations of this quality agreement 	X	X	
<ul style="list-style-type: none"> Only persons with the necessary awareness, skills, competence and training shall be assigned responsibilities in the product associated with this agreement. 	X	X	
<ul style="list-style-type: none"> Provide adequate number of personnel qualified by appropriate training and experience to perform and supervise the manufacture, testing, packaging and disposition of the Product. 	X	X	

Duties	I Austin (Site)	C&G Labs (Supplier)	Comments
Visits to Manufacturing Sites			
<ul style="list-style-type: none"> Supplier to allow Site to visit facility(s) to review any activities pertaining to this quality agreement. 	X	X	This includes Supplier Quality Audits.
<ul style="list-style-type: none"> Supplier to allow I Notified Body to conduct unannounced audits 	X	X	
Purchasing Controls			
<ul style="list-style-type: none"> Supplier shall acknowledge all purchase orders within 5 days 		X	
<ul style="list-style-type: none"> Have approved written procedures in place for qualification (including audits) of suppliers that provide GMP-materials and services. 		X	
Production and Process Controls			
<ul style="list-style-type: none"> Sub-contractor validations 		X	Supplier shall ensure that any outsourced processes that cannot be 100% verified, are validated by the sub-contractor.
<ul style="list-style-type: none"> System to ensure the proper identification and traceability during handling, storage and distribution (Product Classification dependent) of Product 		X	Products shall be traceability by lot number/batch
<ul style="list-style-type: none"> Maintain calibrations and preventive maintenance procedures and schedules for equipment/instruments used in the manufacture, packaging, testing and validation/verification of the Product. Include calibration tagging where appropriate. 		X	
<ul style="list-style-type: none"> Requirements for Certificates of Analysis / Conformance 		X	
<ul style="list-style-type: none"> Document and review (including calibrations performed by Sub-Contractor) manufacturing equipment calibration data and make available to I for onsite review upon request 		X	
<ul style="list-style-type: none"> Implement and document specifications for raw materials, packaging materials, Product labeling, and processing aids that would likely affect Product quality. 		X	

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<ul style="list-style-type: none"> Have approved written procedures for all required in-process sampling and testing. 		X	
<ul style="list-style-type: none"> Process equipment must be uniquely identified, status tagged and managed with an equipment history log or equivalent system. Process lines will be appropriately identified. 		X	
<ul style="list-style-type: none"> Validated/qualify as necessary all critical systems, utilities and equipment/instruments used for the manufacture and control of Product (Installation Qualification (IQ), Operational Qualifications (OQ), and/or Performance Qualification (PQ)). 		X	
<ul style="list-style-type: none"> Maintain shipping records 		X	