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Supplier Quality Agreement

Note: Please delete Notes and replace/delete "Blue Font" text with applicable information throughout this document.

This form is a template and the sections of this Quality Agreement may be revised as required.

SUPPLIER QUALITY AGREEMENT
BETWEEN
CCINTEGRATION INC.
AND
[Supplier Name]

This Supplier Quality Agreement ("Quality Agreement") is entered into by and between _____ having a principal place of business at _____hereafter referred to as ("Supplier") and CC Integration Inc. having a principal place of business at 2060 Corporate Ct, San Jose, CA 95131, hereafter referred to as ("CCI"). The Quality Agreement is effective as of the date of last signature by the parties below.

1.0 Scope

1.1 **Scope**

The parties have entered into a separate written agreement from this Quality Agreement under which Supplier will provide to CCI the products and/or services (the "Products") listed in Section 1.2 below. This Quality Agreement defines the obligations of the parties to ensure that the Products satisfy CCI quality and regulatory requirements.

1.2 **Products and Services Covered by This Agreement**

Fill in Part Numbers

1.3 **Supplier Site(s)**

Supplier manufactures the Products at or provides Services at the sites listed below.

Address:

2.0 Regulations, Standards and CCI Requirements

- 21 CFR § 820 Quality System Regulation
- ISO 9001:2015 Quality Management Systems
- ISO 13485:2003/2012 Quality Management Systems

3.0 Quality Requirements

3.1 Quality Representative. Supplier will designate a quality representative that will be responsible for acting as a liaison with CCI through CCI's designated representative(s) as the point person for any quality issues, for obtaining any regulatory approvals or certifications required for the Products and for maintaining and updating Specifications in accordance with CCI's written instructions. Supplier shall provide CCI, upon request, with copies of any documentation relating to applicable regulatory approvals or certifications for the Products and/or Supplier sites.

3.2 Quality Management System. Supplier's facilities will be certified to conform to the requirements of ISO 9001 and/or ISO 13485 or successor standards or their equivalent at all times in manufacturing and delivering the Products under this Agreement and will provide a copy of the certificate to CCI. Supplier shall inform CCI of any changes to Supplier's quality management system or certifications. This includes certification, re-certification or withdrawals. If a Supplier has no third-party quality system certification, at minimum, the Supplier must meet all the quality requirements of this Section.

3.3 Periodic Meetings/On-Site Visits. CCI and Supplier will have periodic meetings, which may be in the form of regularly scheduled meetings (face to face or conference call), Supplier quality/business review or impromptu meetings as required. Supplier shall allow CCI personnel access to Supplier's facility or facilities used in the manufacture or testing of Products for observation, review for Product issues, etc.

3.4 Specifications. CCI shall define the specifications for Products (the "Specifications") in the applicable purchase order for the Products. This may include drawings, references to commercial specifications and identification of applicable standards.

3.5 Certificate of Conformance. Supplier agrees to sign and provide a certificate of conformance (the "Certificate of Conformance") for each shipment of Product confirming that all the materials processes, and/or finished product supplied under that order are specified and conform to the Specifications as well as the applicable Product environmental compliance standard (RoHS/REACH). Upon request Supplier will provide applicable signed certificates, examples of which include but are not limited to, material certificates, special processing and Product environmental compliance specification such as RoHS/REACH.

3.6 Buildings. Supplier's facilities in which the Product is handled, stored, packaged, labeled or otherwise processed shall be orderly and of suitable design, size, construction and location, including, maintaining: (i) adequate lighting, ventilation and water supply for the activities relating to the Product; (ii) space for performing the activities; and (iii) the ability to separate discrete operations or processes relating to the Products in order to prevent mixing or other contamination of Product. Supplier will notify CCI in writing with respect to proposed changes to facilities, related to the Product prior to the implementation of such changes.

3.7 Document Control. Supplier shall establish a system for creating, controlling, revising and obsoleting documents throughout the history of the Product and Product life cycle.

3.8 Qualification and Training of Personnel. Supplier will ensure all of its personnel engaged in the storage, handling, packaging, distribution or other processing of the Products have the training and experience sufficient to perform their assigned functions in accordance with all applicable laws.

3.9 Inspection at CCI. All Products are subject to CCI's inspection and test before final acceptance at CCI's facility. If any Product delivered under this Agreement fails to conform to the Specifications, CCI shall notify Supplier of such failure, and Supplier shall promptly deliver conforming Products to CCI. If an inspection or test is made on Supplier's premises, Supplier shall provide CCI's inspectors with reasonable facilities and assistance at no additional charge.

3.10 Production and Process Controls. Supplier shall develop, conduct, control and monitor production processes to ensure that the Product conforms to Specifications. Supplier shall assure that production equipment and quality measurement equipment, including mechanical, electronic, automated, chemical or other equipment, are: (i) suitable for the intended use; (ii) capable of producing valid results; (iii) operated by trained personnel; and, (iv) properly calibrated to the appropriate and suitable standard. If the output of a Supplier's process is not fully verified by

subsequent inspection or test, the Supplier shall validate the process. The Supplier shall create a validation protocol (describing the planned activities) and a validation report (documenting the outcome of the planned activities). A change or a deviation from a validated process shall be reviewed and if appropriate revalidated. Supplier shall keep records of the validation and revalidated activities and make them available to CCI upon request. If requested by CCI, Supplier shall create and maintain a process map, process failure modes and effects analysis (pFMEA), and process control plans for all steps from receiving through shipping.

3.11 Supplier Acceptance Testing/ First Article Inspection. Supplier shall be responsible for conducting appropriate testing and/or conformance inspection (incoming, in-process and final) to ensure that the Product will function reliably conforms to the Specifications. For all new part numbers and subsequent changes supplier will perform a first article and provide a copy of the report to CCI.

3.12 Nonconforming Product. Supplier shall establish and maintain procedures to identify, control and recall Product that does not conform to or fulfill the Specifications. Such procedures shall address the identification, documentation, evaluation, segregation and disposition of nonconforming Product. Nonconforming Product shall not be used without the prior written consent of CCI.

3.13 Corrective and Preventative Action. CCI may initiate a Supplier corrective action request ("**SCAR**") when CCI identifies product/process nonconformity. Supplier shall investigate the cause of the nonconformity and provide to CCI, a corrective action plan no later than thirty (30) calendar days of receipt of a SCAR. Supplier shall implement the agreed corrective actions and effectiveness check within the agreed timeframe and provide the records to CCI.

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

3.15 Product Records. Supplier shall retain (and if applicable shall cause its affiliates and subcontractors to retain) detailed written records of all Supplier activities relating to the Product (collectively referred to as the "**Product Records**"). Information included or referenced in the records includes finished Product and package labels and labeling, label accounting information (labels/labeling produced or issued, used, sampled, rejected/destroyed), information regarding any environmental monitoring that takes place during manufacturing and, if required, testing, copies of release testing, if any, performed by Supplier, process deviations and approved process change if any.

3.16 Records Retention. Supplier shall retain (and shall require any affiliates and subcontractors to retain) all Product Records for a period of time equivalent to one year past the design and expected life of the Product or the medical device in which the Product is intended to be included, which is not less than seven (7) years following Product manufacture. Supplier shall not alter, destroy or otherwise dispose of any Product Records without CCI's prior written authorization. Supplier shall provide copies of any or all Product Records to CCI within three (3) business days from the date of CCI's written request for any Product Records.

3.17 Engineering and Manufacturing Changes. Supplier shall notify CCI in writing for review and approval prior to implementing (i) any changes which will affect the form, fit or function of any of the Products, (ii) any change to Supplier's part number for a Product, (iii) any process changes (iv) any changes that require CCI or a subcontractor to perform any work on items that interoperate with the Product, including but not limited to software updates, (v) any changes in packaging and labelling or (vi) any changes which require CCI or a subcontractor to perform any retesting of the Product or which would invalidate safety or regulatory approvals (vii) changes in the location of manufacture of the Product. CCI shall have the right to accept or reject the proposed change. Supplier shall also provide notice to CCI of any name change.

3.18 No Deviations. Supplier will not deviate from the Specifications (including, without limitation, approved procedures, drawings, methods or specifications concerning the Product) without CCI's prior written consent.

3.19 Use of Affiliates and Subcontractors. From time to time CCI may authorize in writing third parties by CCI to construct, manufacture and/or assemble products or subassemblies for CCI. Supplier will not use any affiliate or subcontractor for any supply of components or services related to the Product without notifying CCI in advance in writing. CCI may specify change control procedures applicable to the provision of services by such affiliate or subcontractor in addition to or in accordance with Section 3.17 (Engineering and Manufacturing Changes).

3.20 Sub-Tier Suppliers. Supplier shall implement and maintain sub-tier supplier control. Control measures shall be sufficient to ensure that sub-tier suppliers' manufacture, package, label, test and release of Products are consistent with this Quality Agreement.

3.21 Supplier Audit. Upon reasonable advanced written notice to Supplier, CCI shall have the right to conduct an audit of the Supplier with respect to the Product and Supplier's compliance with the terms of this Agreement (a "**Quality Audit**"). Supplier shall also permit CCI, with or without notice, to conduct additional Quality Audits as CCI may reasonably require to address: (i) quality problems relating to the Product; (ii) compliance with applicable requirements and (iii) safety issues. Supplier shall provide CCI with access to Supplier's facilities, Product records and/or operations to conduct the Quality Audit during normal business hours. Supplier shall not in any manner unreasonably delay, condition or otherwise interfere with CCI's right to conduct the Quality Audit.

3.22 Corrective Action Plan. In the event that a Quality Audit finds or identifies any condition(s) that are not in compliance with this Agreement, Specifications or other quality system issue (hereinafter an "**Observation**"), then Supplier shall be responsible to provide CCI with a written corrective action plan within a reasonable timeframe not to exceed thirty (30) calendar days after the receipt of the Quality Audit report. The corrective action plan shall, at a minimum, capture the results of an investigation into the cause of the Observation, a description detailing Supplier's steps for addressing each Observation and implementing proposed corrective and preventive actions and a schedule indicating when such corrective and preventive actions would be effective.

3.23 Design Controls. This subsection applies only to suppliers that are designing products for CCI. Supplier shall establish and maintain a design control procedure to define the stages of design and/or development processes, perform verification and validation activities appropriate to each design and/or development stage and define the responsibilities and authorities for design and/or development activities. Supplier shall maintain design plans that describe or reference the design and development activities and define responsibility for implementation. Design documentation shall be available to CCI upon request.

4.0 REGULATORY COMPLIANCE

4.1 Regulatory Inquiries. Supplier shall promptly inform CCI of the existence and substance of any inquiry or investigation related to the Products initiated by any government authority or certification agency.

Regulatory Inspections. Supplier will notify CCI Quality Assurance within five (5) business days of the notification or first day (whichever is earlier) of a regulatory inspection or audit, announced or unannounced (such as by a EU notified body, FDA, Japanese PAL or ANVISA), where such inspection or audit applies to a Supplier facility where the Products are manufactured) or is an inspection or audit of CCI's places of manufacture and the scope of such inspection or audit includes

the third party facilities where CCI's products are manufactured. Supplier shall provide CCI the opportunity to be present at such inspections or audits. Supplier shall cooperate fully with any such inspections or audits. Supplier shall provide to CCI, within five (5) days of its submission or receipt by Supplier, copies of the inspection or audit observations and copies of responses to regulatory observations pertaining to CCI product (For example: FDA 483 Form). Supplier shall immediately correct any deficiencies identified in the regulatory inspection.

4.2 Product Complaints/Reports. Supplier shall promptly provide to CCI any information received by Supplier regarding real or potential deficiencies or defects in the Products and any information that might otherwise constitute a complaint about the Products or would reasonably be considered material to the safety of the Products and/or the Product's intended use. Each party shall reasonably cooperate with the other in sharing any information that may constitute a complaint related to the Products or services. Supplier shall at all times reasonably cooperate with any requests arising from a CCI investigation, inspection or inquiry regarding the Products.

4.3 Recalls. CCI shall have the sole authority to declare a recall of any Products if CCI believes there is or may be a potential significant health hazard or non-compliance with applicable government regulations.

5.0 GENERAL

5.1 Term of Agreement. This Quality Agreement may be terminated by either party for any reason or for no reason upon written notice of termination to the other party.

5.2 Entire Agreement, Amendments. This Quality Agreement, including any Appendices and other attachments, is the complete, final and exclusive statement of the terms of agreement between the parties relating to the subject hereof and merges and supersedes all prior and contemporaneous understandings and representations, written and oral. No amendment to this Quality Agreement is effective between the parties unless mutually agreed, in writing and signed by authorized representatives of both parties.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives.

CCINTEGRATION INC.	[Supplier Name.]
By: _____	By: _____
Name: _____	Name: _____
Title: _____	Title: _____
Date: _____	Date: _____

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Supplier Quality Agreement

Supplier to provide the following as applicable.

Appendix A: Vendor DOA and warranty policy

Appendix B: Pricing, terms and condition

Appendix C: Vendor contact information include Quality Team member

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Supplier Quality Agreement Revision History

Revision #	Date of Revision	Summary of Change
A	6/7/2019	Initial release