

General Quality Requirements for Purchased Products

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General Quality Requirements for Purchased Products

Procedure Description

1. Purpose

This document sets out the general quality requirements, and the supplier quality agreement for the quality of Goods and/or services as supplied by Suppliers ("Supplier") to Celestica LLC or any of its affiliates ("Celestica").

2. Scope

By delivering to Celestica any components or manufacturing materials (the "Goods"), the Supplier agrees that this Agreement sets out the terms and conditions relating to the quality of Goods which the Supplier supplies.

This Agreement shall replace any previously agreed terms regarding quality to the extent they conflict with these terms.

Any Supplier supplying Goods into Celestica's HealthTech business shall be notified as such, either at the time this document is formally issued for review, or as specifically identified within the individual quality specification (the "QSPEC") of the part. In these cases, CELQ-001-SPEC-7 (DOC#0073861) Appendix A shall also apply.

Changes at this revision are indicated by | in the left hand column and blue text.

3. Responsibilities

- Suppliers are responsible for ensuring that they read and understand the requirements of this document:
- In conjunction with the acceptance of Purchase Orders ("PO")
- Prior to agreeing or signing the acceptance of this requirement when formally requested to do so as part of Celestica's supplier qualification program.

3.2 Supplier's are also responsible for advising Celestica of any requested exclusions to the content of this document.

3.3 Celestica's Commodity Management department are responsible for ensuring that suppliers have access to this document from the Supplier Portal.

3.4 Celestica's Commodity Engineering groups are responsible for:

- ensuring that suppliers are issued a copy of this document as part of the formal supplier qualification activities,
- responding to supplier queries on the content or requested exclusions,
- responsible for ensuring any queries or exclusions are formally agreed or declined, including notification back to the supplier of that decision,
- recording the agreement or signed document as part of the supplier qualification activities.

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4. General Quality Requirements

If a conflict arises between the requirements of this document and other Celestica documents, the following order of precedence shall apply:

- (a) Celestica's Standard Purchasing Terms and Conditions
- (b) Purchase order
- (c) Engineering drawings
- (d) Engineering Specifications and Material Specifications
- (e) The individual QSPEC
- (f) This General Quality Requirements for Purchased Parts
- (g) Referenced standards

4.1 General Quality Requirements:

4.1.1 The Supplier shall not ship Goods to Celestica which deviate in any manner from the Celestica specification for the Goods, without prior written consent by Celestica. This includes the shipment of "better than" specification parts in place of the requested specification, see section 4.11 Waivers.

4.1.2 Where the Supplier is a franchised distributor of the part the Supplier shall ensure that the parts sent to Celestica are from the AVL as shown on the Celestica QSPEC. The franchised distributor warrants that the parts shipped have been obtained from the official OEM sales channel.

4.1.3 The Supplier shall ensure that all Goods which are identified as requiring manufactured date codes carry manufactured date codes that are not older than 24 months at time of receipt by Celestica or as otherwise specified in the Celestica QSPEC. Where this cannot be met the supplier shall ensure a specific agreement or waiver is in place [that details the justification, proven by testing and analysis, that parts received by Celestica, beyond our standard 24 month requirement, have no functional nor reliability concerns.](#)

Celestica retains the right to refuse to accept parts with dates codes >24 months at point of receipt if an agreement or waiver is not in place.

4.1.4 The Supplier shall ensure and only provide Goods or parts which meet the relevant technical specifications, appropriate to the goods they supply, namely:

- In the case of custom, or customized parts the parts meet the required technical specifications as issued by either Celestica or the customer,
- In the case of catalogue parts the parts meet the Supplier's own manufacturing specification and any industry related specification,
- Where the parts are supplied on Tape & Reel they conform to the *EIA-481* standard,
- The Supplier will ensure and only provide Goods that are produced, repaired and packed under electrostatic "safe" conditions as advised in JESD625, ANSI S20.20, IEC61340-5-1 or equivalent.

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4.1.5 The Supplier shall ensure that the parts meet the relevant Cosmetic Requirements for the parts as defined on the part drawing, a Celestica issued Cosmetic Standard or a customer issued Cosmetic Standard.

At a minimum the Supplier shall ensure that the following is met:

- All parts shall be free from Oil, Grease, Dirt and other Contaminants which may result from the processing or manufacture of the part and which do not form part of the functional requirements of the part,
- All Mechanical parts shall be free from Rough and Sharp Edges, Flash and Burr as defined by component type, technology and industry standards where they exist.
- All Electronic parts which require to be soldered comply with the applicable solderability specifications *IPC/EIA J-STD-002* or *IPC/EIA J-STD-003*
- All applied Labeling shall have defect free and legible printing and labels and nameplates shall be applied squarely to the part and within the defined area as per drawing.

4.1.6 The Supplier shall ensure that all personnel performing work which affects the product quality and / or conformance to specifications, including customer requirements are competent on the basis of appropriate education, training, skills and experience.

4.2 Supplier Quality Management Systems:

4.2.1 Celestica expects the supplier to conduct their activities under appropriately controlled conditions for the product supplied.

Where Celestica requires the supplier to operate under a third party certified Quality Management System ("QMS"), for example ISO9001, Celestica shall make this formally known to the Supplier.

4.2.2 The Supplier agrees to submit to Celestica evidence of the controls in place or copies of the registration certificates upon request by Celestica.

4.2.3 Where the controlled conditions have been deviated from, the supplier agrees that a Waiver request will be required to continue to supply Celestica, see Waiver section 4.11. Examples of such deviated conditions are shown in section 4.11

4.3 Supplier Audits:

4.3.1 The Supplier shall, when requested with a mutually agreeable schedule, allow reasonable access for Celestica to conduct an on-site audit at the Supplier's facilities. The audit shall include all applicable documentation and records.

This agreement to allow audits shall be extended to any Celestica entity, Celestica's partners or Celestica's customer.

4.3.2 Audits may be requested by Celestica for the following reasons:

- *Corrective Action Audit* as a result of a formal CAPA to validate the CAPA and the effectiveness.
- *Process Audit* this may be requested for a variety of reasons, such as but not limited to when a new process is introduced, to support the Supplier to investigate quality issues, as the result of a Supplier PCN.
- *Qualification Audit* in support of Celestica's Supplier qualification process.
- *Conflict Minerals Audit* in support of Celestica's SEC reporting requirement.

4.3.3 The scope of the audit, including the pre-audit, during audit and post-audit activities will be agreed between the Supplier and Celestica.



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4.3.4 In exceptional cases it may be required to conduct on-site audits or verification at short notice. The Supplier agrees to support Celestica's schedule, including the provision when required for audits "next-day" or within 24 hours notice. In these cases Celestica will make direct contact with Supplier on a case by case basis for formal agreement.

4.3.5 The Supplier shall also ensure that when it is relevant to the successful outcome of an audit Celestica may extend the audit to the Supplier's supply base (sub-Supplier). Typical example may be to audit the external plating contractor for the Supplier's products.

4.4 Delivered Quality Requirements:

4.4.1 Celestica and the Supplier's goal is to maintain a *ZERO Defect* Incoming Quality Level (IQL).

IQL is the defect level measured in Celestica's internal process. Component IQL is an ongoing measurement and is reviewed regularly by Celestica.

4.4.2 The Supplier shall maintain records which show that the Goods have been manufactured in a manner to assure compliance with the part specification for either:

- a)** a minimum of five (5) years from date of manufacture as standard, or
- b)** where there is a customer requirement for record retention over 5 years, Celestica will make this requirement known during the contract stages and the requirement will be stated in the QSPEC.

In the case of 4.4.2b the Supplier agrees to support Celestica by adapting their own record retention policy or agrees to work with Celestica on a mutually agreeable process to meet the customer requirements.

4.4.3 Celestica expects the Supplier to use statistical process controls and a supporting process capability analysis at a level appropriate for the products supplied to achieve continuous quality improvement and failure rate reductions. Supplier shall, upon request, provide Celestica with evidence of such process controls and capabilities, including all supporting documentation.

4.4.4 For custom mechanical parts, where the parts are manufactured to a customer or Celestica drawing:

a) Suppliers are required to perform a Ship Lot Audit before shipment by randomly selecting a representative sample of finished Goods and inspecting them to the Celestica QSPEC. The Critical to Function (CTF) dimensions will be shown on the QSPEC and/or referenced drawings. A statistically valid sampling plan shall be used for the Ship Lot audit based on an industry recognized standard (ANSI/ASQC Z1.4 or ISO2859). Results are to be documented, maintained by the Supplier for a minimum of 7 years, or for a longer period as defined within the requirement of 4.4.2, and made available to Celestica upon request.

b) When a lot fails the Ship Lot Audit but in the opinion of the Supplier the product might be 'fit for use', the Supplier is required to notify the Celestica buyer of the non-compliance and ask for a Supplier Waiver prior to shipment. Without a documented Supplier Waiver, the lot is NOT to be shipped. If the failed lot is not deemed to be 'fit for use' or the Supplier Waiver is rejected, the Supplier must not ship the material without some form of remedy (i.e. 100% screening for the defects, rework or correction of the defects, or manufacture of a new lot).

**Celestica™****General Quality Requirements for Purchased Products****4.5 Inspection and Testing:**

4.5.1 Goods purchased by Celestica and shipped by Supplier are subject to Celestica's reasonable inspection, testing, and approval at Celestica's point of receipt or final place of usage.

4.5.2 Chemical and consumables which are added to the final product (e.g. paste, flux, adhesive, conformal coating etc...) may be subjected to surface Insulation Resistance (SIR) testing or an equivalent Material Compatibility testing. This is in addition any requisite functional qualification against market peers.

4.5.3 Celestica shall have the right to reject and refuse acceptance of Goods which are not in accordance with the Supplier's specifications, the specifications of the part, any written contract or agreement or any of the terms of this agreement Spec-7 (DOC#0073861).

4.5.4 Payment for any Goods under the related Purchase Order shall not be deemed acceptance of the Goods.

4.6 Packaging of Goods:

4.6.1 Celestica expects the supplier to package the products which it supplies in packaging suitable for the product being shipped, and to prevent damage and deterioration during the method of shipment.

Where supplier is unsure of packaging requirements Celestica provides a specification document which may be referred to. Celestica's "Packaging and Handling Specification", PK0763-1, is available from the buyer, or through the link www.celestica.com/supplierresources

Where specific packaging requirements are required at a Celestica part number level, they will be formally issued to the supplier through drawings, specifications or other purchasing documents.

4.6.2 For Goods that Supplier identifies as moisture sensitive, the following requirements apply:

- 4.6.2.1** The Goods shall be packaged in an ESD moisture free pack (dry pack).
- 4.6.2.2** The dry pack shall be bar-coded as per the requirements of section 4.7 of this document.
- 4.6.2.3** The dry pack shall have an ESD warning on it.
- 4.6.2.4** The dry pack must contain a moisture indicator that conforms to J-STD-033 or EIAJ standard.
- 4.6.2.5** The dry pack must also contain desiccant, of an appropriate amount and type, so as to conform to the requirements of J-STD-033 or EIAJ standard.
- 4.6.2.6** The dry pack shall have a label indicating the dry pack date and usage window (after dry pack is opened 'hold-on time'), re-baking requirements (temperature, time and number of re-bakes permitted), and where shipments of 500 units or less are packaged in trays, the trays must be bakeable to 125 degrees C.
- 4.6.2.7** All moisture sensitive components shall comply with J-STD-033, J-STD-075 and J-STD-020 (or EIAJ ED4701/300-3) requirements where applicable.
- 4.6.2.8** Notification of changes to the moisture sensitivity rating by the Supplier is required through the Celestica Notification of Change process, see section 4.8 below.

4.6.3 The Supplier shall not provide Celestica with Goods that have reels or internal boxes that contain mixed date and/or lot codes. The Supplier shall advise Celestica if this is not possible, and then Supplier will ensure that there be no more than two date codes in one unit pack container (reel, tube or tray) per internal box. If two date codes are used, the unit pack container and the outside of the internal box should be clearly identified as having mixed date codes and labels must indicate the quantity for each date code.

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4.6.4 The Supplier shall only provide Goods in packaging that is clearly marked in written form with Celestica's name and the relevant delivery address as well as showing Celestica's order number, quantity or gross and net weights.

4.6.5 Celestica expects the Supplier to comply with all relevant provisions of applicable health and safety legislation, and shall ensure that Goods which are potentially dangerous to health or safety shall be delivered only in suitable protective packing or containers, and that the external surface of such packing and/or containers shall be clearly labeled so as to indicate any hazards to health or safety involved in handling and using Goods and as to the method of safe handling of Goods.

4.7 Labeling and Traceability:

4.7.1 Unless otherwise agreed in writing, Supplier shall ensure that the bar code format as described in Celestica standard CELQ-033-STD-51 is used for the inner most level of part packaging and outer levels of packaging. In particular Celestica requires that the barcode format is CODE 39.

4.7.2 Each unit of electronics parts i.e. each reel, tube, tray, etc., shall have an ESD warning on it where applicable and shall also be labeled as per 4.6.1.

4.7.3 All parts, electronic and mechanical shall have the inner most level of packaging, "Final Carrier", labelled with a barcode in Code 39 according to Celestica's barcode specification CELQ-033-STD-51.

Specifically the label shall contain:

- (a) Celestica's Part Number,
- (b) Manufacturer's Part Number,
- (c) Traceability Code
- (d) Date Code,
- (e) Quantity,
- (f) Supplier ID Code,
- (g) Country of Origin.

4.7.4 The Supplier shall ensure that procedures are in place to manage the labeling process and to avoid mislabeling of Goods.

4.8 Change Control:

4.8.1 No change, substitution or modification of any Goods, component parts, tooling, and sources of raw materials, processes, or manufacturing sites, or shipment of alternate parts may be made without prior notification to Celestica. The Supplier shall notify Celestica by sending the details of the change to pcn@celestica.com

For classification of types of change refer to legacy document CELQ-033-POL-2 (DOC#0073917).

4.8.2 Where changes are necessary the Supplier shall provide Celestica ninety (90) days written notice prior to the change taking place, except in the case of End of Life ("EOL") where an extended notice period is defined in 4.8.3.

4.8.3 Where the changes relate to the discontinuance or EOL of the Goods then the Supplier shall provide Celestica with a notification period of:

- 6 months prior notification of Last Time Buy dates
- 12 months prior notification of Last Time Ship dates.

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4.8.4 The Supplier shall ensure Change Notifications contain a sufficient level of detail for Celestica to understand the change taking place and judge the impact.

All Change Notifications should have a unique tracking identification number and contain at a minimum:

- Reason for the change
- Full description of the change,
- List of all affected manufacturer's part numbers, including Celestica part numbers where possible,
- Proposed implementation date, which must be minimum 90 days after notification,
- All data necessary to show that the change has been fully verified and validated,
- Availability of samples for the change,
- Identification to provide traceability of the change eg, date code, special marking etc.
- Supplier contacts

4.8.5 All Change Notifications are required to be submitted to Celestica's central PCN team along with all necessary data to pcn@celestica.com

4.8.6 In many cases EOL has to be tightly managed and may involve significant redesign by Celestica or our customer. In these cases the Supplier acknowledges to provide the necessary support and flexibility to accommodate the management of the EOL.

4.8.7 Any concerns, requests for additional information, extension requests or rejection of the Supplier's PCN will be communicated by Celestica to the Supplier contact within 30 days of original receipt.

4.8.8 The Supplier must assure that Celestica are detailed as a customer in the Supplier's internal Change Notification processes and procedures. Where the Supplier has OEM agreements for Change Notification, Celestica must also be written into the process to receive the Change Notification **in parallel to, and at the same time as** the OEM.

4.9 Product Quality Notifications:

4.9.1 The Supplier shall notify Celestica immediately when they suspect or have reason to suspect that non-conforming Goods have been shipped to Celestica.

4.9.2 All Product Quality Notifications should contain at a minimum:

- Details of the suspected non-conformance,
- Time period over which the suspect parts were produced and shipped, including number of lots shipped to Celestica,
- List of the affected part numbers,
- List of date code, lot code or other identification code to allow the suspect Goods to be quarantined from use,
- Details of any method of screening if applicable,
- Details of returns management including valid RMA number and "ship to" details.

4.9.3 All Product Quality Notifications are required to be submitted to pcn@celestica.com



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4.10 Control of Non-Conforming Product:

4.10.1 Where Goods are found to be non-conforming and are rejected by Celestica, the Supplier shall be notified. Agreement of non-conformance, the disposition of the rejected Goods and any further actions shall be agreed.

4.10.2 Rejected Goods, or non-conforming Goods which are found by Celestica, or which are advised to Celestica by Supplier under the Quality Notice process, see section 4.9, may be returned to Supplier as the first option, or held by Celestica, at Supplier's risk and expense.

4.10.3 Where the Goods are agreed to be non-conforming the Supplier acknowledges that Celestica are not expected to fund any further inspection or screening of non-conforming Goods. Where inspection or screening is required as a necessary and agreed action, the Supplier shall provide this service to Celestica by Supplier representatives or through a 3rd party authorized by Supplier to conduct such activity, or by other mutually agreeable means.

Where this activity (inspection, screening or rework) relates to Celestica's product ie WIP or Finished Goods, the activity, the decision on who conducts the activity and the funding of such activity shall be agreed with the Supplier.

4.10.4 The Supplier agrees to support Celestica's business needs by supplying Celestica with the appropriate Returned Material Authorization ("RMA") to return non-conforming Goods to the Supplier.

The RMA requirement will be driven the situation on a case by case basis, Supplier agrees to support the following typical situations:

Urgent Requests within 24 hours, typically these are line down situations where Supplier's top management will be made aware of the urgency

Major Requests within 48 hours, typically these are situations where a specific problem is affecting Celestica's ability to build product

Standard Requests with an RMA response time mutually agreed and documented, typically these may be routine returns.

4.10.5 The RMA response shall include details including:

- Unique RMA number which provides tracking of the activities,
- Shipment address where the non-conforming Goods are to be shipped, along with contact name,
- Details of any special shipping requirements including specific packaging if required,
- Details of Supplier's required shipping method, courier and account information to arrange the shipment,

4.11 Waivers:

4.11.1 The Supplier must be in possession of a **Celestica approved** Waiver prior to dispatching Goods where, but not limited to:

- the Goods intended for dispatch do not conform to the specifications ordered, including "better than" parts,
- the manufacturing controlled conditions have been exceeded, example; ambient temperature out of control limits,
- the parts were manufactured on a process undergoing qualification,
- the Supplier's QMS registration has been expired, terminated or suspended, see section 4.2.

General Quality Requirements for Purchased Products**4.12 Corrective Action and Preventive Action (CAPA):**

4.12.1 The Supplier shall implement the necessary CAPA for non-conforming Goods when requested to do so on receipt of a Celestica SCAR.

The Supplier is required to provide lot / date code information within 24 hours of request by Celestica regarding the lot or date codes affected by the non-conformance, plus any lot or dates codes which could potentially be affected by the non-conformance.

4.12.2 The Supplier shall ensure that the CAPA investigation includes:

- Confirming the failure mechanism
- Taking steps to contain the problem and minimize the effects of the non-conforming Goods,
- Define the root cause of the problem,
- Take Corrective Action ("CA") for the incident,
- Investigate PA opportunities to prevent future non-conformities
- Verify the Effectiveness of the CAPA to eliminate the problem

4.12.3 The Supplier shall implement CAPA in a timely manner in line with Celestica's requirements of SCAR timelines which are:

Urgent SCARs shall have a CAPA plan issued *within 9 days*.

Standard SCARs shall have a CAPA plan issued *within 23 days*.

The SCAR will be issued as Standard or Urgent depending on the severity of the quality incident.

4.12.4 For instances of No Fault or No Defect Found (NTF or NDF) the Supplier agrees to work with Celestica to understand the mechanisms of the perceived non-conformance to achieve a mutually agreeable resolution.

4.13 Environmental Requirements:

4.13.1 The Supplier shall comply with Celestica's environmental requirements as they relate to the Goods being supplied:

- Celestica Environmental Requirements for Purchased Components legacy *CELQ-033-POL-7 (DOC#0075098)*

- Celestica Environmental Requirements for [Purchased Chemicals](#) and [Consumables](#) legacy *CELQ-033-POL-15 (DOC#0075099)*

4.13.2 The Supplier shall, upon request, make available to Celestica any certificate of conformance, material declaration and / or analytical test reports.

4.13.3 The Supplier agrees on behalf of itself and its entire supply chain to adhere to and comply at all relevant times with Celestica's Conflict Mineral Requirements *CELQ-033-POL-63*

[\(DOC#DOC0078175\)](#) (available at <http://www.celestica.com/supplierresources>)

All queries regarding Celestica's Conflict Mineral Requirements should be forwarded to conflictminerals@celestica.com

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5. Definitions, references in italics are listed below:

CAPA:

Acronym for Corrective Action, Preventive Action.

Correction:

Action to eliminate a detected nonconformity. This may or may not involve a corrective Action.

Corrective Action:

Action to eliminate the cause of a detected nonconformity or other undesirable situation (2).

Preventive Action:

Action to eliminate the cause of a potential nonconformity or other undesirable situation (2).

Component:

Any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device (3).

Engineering Specification:

Documents which define and describe requirements and specifications for components and / or manufacturing materials.

Goods:

In this document it refers to any component or manufacturing material supplied to Celestica by a Supplier.

Manufacturer:

The organization which makes the component or manufacturing material which Celestica purchases, this may be different to the "Supplier", see below.

Manufacturing Specification

Documents which define and describe the requirements and specifications for the manufacturing of components or manufacturing materials. For example, this may include the specification of the type of equipment used to perform an activity.

Manufacturing Material:

Any material or substance used in or used to facilitate the manufacturing process, a concomitant constituent, or a byproduct constituent produced during the manufacturing process which is present in or on the finished device as a residue or impurity not by design or intent of the manufacturer (3).

Product or Part Specification:

A document, or set of documents which clearly describe the specifications of a component or manufacturing material. The documents could be Supplier, Customer or Celestica issued and controlled documents.

Quality Management System

Refers to the Supplier's coordinated activities, responsibilities, resources, policies, processes, procedures and documentation to direct and manage their organization with regards to the supplier's quality objectives. Often used to reference international quality standards, including but not limited to ISO9001, ISO13485, TS16949, AS9100.

QSPEC:

The QSPEC is Celestica's quality specification for a Celestica part number. It defines the AVL for the part as well as any special instructions for the Supplier or Celestica use. Each Celestica part number has its own QSPEC.

Supplier:

The entities that receive Celestica's PO and supply the components or manufacturing materials requested by purchase order, the "supplier" may be different to the "manufacturer".

Third Party Certification Body:

Organizations who are independent from a manufacturer, and who are accredited by national government bodies to assess and issue certifications to organizations in relation to international standards eg BSI, TUV

Waiver:

Celestica's internal process, and nomenclature for a deviation or concession for off-spec approvals.

References: Any hyperlink references are outside of the control of Celestica and are listed only to identify the reference source.

(1) FDA General Controls for Medical Devices

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/ucm055910.htm>

(2) Global Harmonization Task Force GHTF/SG3/N18:2010 Now available through the International Medical Device Regulators Forum (IMDRF) after the disbanding of the GHTF in November 2012. <http://www.imdrf.org/documents/doc-ghtf-sg3.asp>

(3) FDA 21CFRPart820.3 Definitions

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=820.3>

General Quality Requirements for Purchased Products**6. Appendix A:****Additional Quality Requirements for Purchased Parts (Celestica HealthTech)****A1 Purpose:**

The purpose of Appendix A is to set out the quality requirements and the supplier agreement, in addition to those already documented in the main body text of legacy document CELQ-001-SPEC-7, "Spec-7", (DOC#0073861) for the quality of Goods and/or services as supplied by Suppliers ("Supplier") to Celestica LLC or any of its affiliates ("Celestica") for use in Celestica HealthTech business.

A2 Scope:

By delivering to Celestica HealthTech any components or manufacturing materials (the "Goods"), the Supplier agrees that this Appendix A sets out the terms and conditions, in addition to Spec-7 (DOC#0073861) relating to the quality of Goods which the Supplier supplies.

This Appendix A is only required to be agreed and signed by those suppliers qualified by Celestica for Celestica HealthTech.

Where similar or conflicting requirements appear in Appendix A and Spec-7 (DOC#0073861), the requirements in Appendix A shall take precedence.

Appendix A defines *mandatory requirements* related to Celestica's healthcare regulated products. The supplier will be expected to agree to these requirements when they are supporting such products, or to provide a mutually agreeable alternative which meets the intent of these requirements.

A3 Definitions, in addition to Spec-7 (DOC#0073861):**Adulterated:**

Subjected to the FD&C Act, "adulterated" in relations to medical devices includes, but is not limited to products which contain filthy, putrid or decomposed substances, is prepared, packed or held under unsanitary conditions, is in violation of Good Manufacturing Practice requirements (1)

Medical Device

The definition of a Medical Device is described fully by:

EU Directive 93/42/EEC Article 1 :

<http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993L0042:en:NOT>

US FDA Medical Device Classification:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm>

Misbranded:

Within the scope of this document this refers to any component or manufacturing material where there is false and / or misleading information on the label, whether this is added intentionally or otherwise. For a full description related to finished medical devices use the reference link (1).

A4 Additional Quality Requirements:

In addition to section 4.1.6 of Spec-7; The Supplier shall ensure that all personnel performing work which affects the product quality and / or conformance to specifications are competent on the basis of appropriate education, training, skills and experience, including regulatory knowledge and experience.

In addition to section 4.1.6 of Spec-7; As part of training personnel shall be made aware of typical defects which could arise from not performing their specific tasks and activities.

In addition to section 4.1.6 of Spec-7; Personnel who are responsible for performing inspection or quality assurance activities shall be made aware of typical defects which they could encounter as part of their job function.

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In addition to section 4.2 of Spec-7; Suppliers who supply Goods which are considered in their own right to be Medical Devices shall only provide such Goods when the Supplier is ISO13485 and/or FDA registered to manufacture the Goods.

Where appropriate this shall be identified on the individual QSPEC for the part number being supplied, but Supplier is expected to be aware if their own products are defined a medical device as identified in the definitions above.

In addition to section 4.2 of Spec-7; Suppliers of Goods used in healthcare products require the Supplier to notify Celestica of any changes to QMS registration through the PCN process within 48 hours of those changes occurring, or provide a suitably agreeable method to communicate those changes.

In addition to section 4.2 of Spec-7; Changes to registrations are also deemed to require notification, including any alterations to certificate scope and period of validation, as well as change of Registrar / Notified Body, upgrade to another QMS and / or expiration or termination of registration.

In addition to section 4.3.1 of Spec-7; The agreement to allow audits shall be extended to a regulatory authority if required to do so.

In addition to section 4.4.2 of Spec-7; Supplier acknowledges that typical document retention periods in the HealthTech market may be in the region of 15 years and upwards. In this case the Supplier agrees to support Celestica by adapting their own record retention policy or agrees to work with Celestica on a mutually agreeable process to meet the customer or regulatory requirements.

In addition to section 4.7 of Spec-7; Suppliers supplying Goods for healthcare products shall ensure that procedures are in place to manage the labeling process and to avoid misbranding and the use of false and / or misleading labels.

Misbranding of Goods covers, but is not limited to:

- Labeling which includes false or misleading information,
- Duplication of Serial Numbers, batch codes or lot codes
- Wrong Identification of Part Numbers & Revision levels,
- Wrong Identification of Tolerance Bands, Bin Numbering, Quality Classifications etc,
- Labeling Goods with a single lot code but package contains multiple lot codes,

unless otherwise notified.

In addition to section 4.8 of Spec-7; Changes related to Goods supplied for Celestica Healthcare products, the Supplier shall not make the change without Celestica's prior written consent.

This will be confirmed to the Supplier within thirty (30) days of receipt of the Supplier's notification.

In addition to section 4.9.1 of Spec-7; The Supplier acknowledges that failure to notify Celestica of non-conforming product could result in Celestica's built product being considered adulterated. Supplier understands that adulterated products may result in further actions by regulatory authorities down to Supplier level.

In addition to section 4.12.2 of Spec-7; The supplier agrees to verify, or support Celestica in verifying that the CA proposed has had no adverse impact on the device or it's intended use.



Celestica™

General Quality Requirements for Purchased Products

References: Any hyperlink references are outside of the control of Celestica and are listed only to identify the reference source.

(1) FDA General Controls for Medical Devices

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/ucm055910.htm>

(2) Global Harmonization Task Force GHTF/SG3/N18:2010 Now available through the International Medical Device Regulators Forum (IMDRF) after the disbanding of the GHTF in November 2012.

<http://www.imdrf.org/documents/doc-ghtf-sg3.asp>

(3) FDA 21CFRPart820.3 Definitions

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=820.3>

A5 Supplier Quality Agreement (HealthTech only) :

Supplier Name:	
Supplier Site:	
Site Address:	
Supplier Quality Agreement Accepted & signed by:	
Job Title:	
Direct Contact Tel:	
Direct Contact email:	

Celestica Agreement* signed by:	
Position:	

**Celestica Agreement only required when exclusions or amendments are requested by a supplier.*

Celestica sign-off must be by a Celestica Manager or above with authority to agree to changes. All exclusions and amendments must also go through HealthTech QA&R for agreement or sign-off depending on the request.

A5.1 Supplier Acceptance: mark in the box which applies

<input type="checkbox"/>	Accepted
<input type="checkbox"/>	Accepted with Requested Exclusions / Amendments**
<input type="checkbox"/>	Rejected

***strikethrough as required*

A5.2 Where the Supplier has “Accepted with Requested Exclusions or Amendments” these should be listed below. The Supplier shall not make changes to the main body of text within this Supplier Quality Agreement as this will be deemed to make the document invalid. Celestica agreement to exceptions will be dealt with on a case by case basis. Formal notification of our decision shall be given.

General Quality Requirements for Purchased Products

Clause:	Supplier Comments on requested exclusion or amendment (<i>add extra sheets as necessary</i>)

A5.3 Where the Supplier has “Rejected” this agreement the Supplier warrants that they cannot meet Celestica’s Quality requirements for HealthTech business and deems that the necessary remedial actions cannot be implemented.

General Quality Requirements for Purchased Products**7. Related Documents:**

7.1 The standard documents listed below (the “Related Documents”) are referenced in this Agreement and Supplier acknowledges and agrees that it has a copy of the Related Documents which are applicable to its business in its possession on the Effective Date of this signed agreement, and that the terms of the Related Documents apply to this Agreement. Where there are doubts as to the applicability of documents the supplier should contact the relevant Celestica Commodity Manager or Engineer.

7.2 Celestica’s expectations are that the Supplier shall flow down through their supply chain the Related Documents and any other applicable requirements issued by Celestica to the Supplier.

7.3 Note that drawings and related technical data may be export controlled and licensable under US, Canadian or other national country law. Such government regulation is typically applicable to, but not limited to the technologies listed below:

Aerospace and Defense, High Performance Industrial (not consumer), Computing and High Performance Telecommunications (notably those using encryption technologies).

Please check with Celestica before sending drawings or other technical data internationally within your own organization as well as with third-parties.

7.4 Supplier agrees to adhere to and comply with the terms and standards set out in the Related Documents which are relevant to the Supplier’s business, (as they are updated and amended from time to time), and shall be responsible for ensuring that it is always in possession of the latest update version of the Related Documents.

Please use the form in Appendix A to list any which do not apply to your business.

Due to copyright restrictions non-Celestica standards cannot be issued by Celestica. Please refer to the specific industry or standards body for the document, for example JEDEC standards are available through www.jedec.org.

Celestica standards are available through

<http://www.celestica.com/SupplyChain/SupplyChain.aspx?id=798>

A list of industry recognized (external) and Celestica standards are provided in the tables which follow.

7.5 It is the Supplier’s sole responsibility to have the latest version of the part number specific Celestica QSPEC (Individual QSPEC) in its possession on the effective date of the purchase order. The Individual QSPEC can be requested from the Celestica buyer or downloaded from Celestica’s Supplier Web Portal. Supplier can request online QSPEC access by sending an email to AskQSPECS@Celestica.com. The Supplier agrees that it shall be assumed that the Supplier has the latest version of the part number specific Celestica QSPEC (Individual QSPEC) in its possession on the effective date of the purchase order.

General Quality Requirements for Purchased Products

Ref	External Document Name	Document Number	Current Revision
a	8 MM THROUGH 200 MM EMBOSSED CARRIER TAPING AND 8 MM & 12 MM PUNCHED CARRIER TAPING OF SURFACE MOUNT COMPONENTS FOR AUTOMATIC HANDLING	EIA-481	See standards agency
b	HANDLING, PACKING, SHIPPING AND USE OF MOISTURE/REFLOW SENSITIVE SURFACE MOUNT DEVICES	IPC/JEDEC J-STD-033	See standards agency
c	CUSTOMER NOTIFICATION OF PRODUCT/PROCESS CHANGES BY SOLID-STATE SUPPLIERS	JEDEC standard No. 46 (JESD46)	See standards agency
d	COMPONENT QUALITY PROBLEM ANALYSIS AND CORRECTIVE ACTION REQUIREMENTS (INCLUDING ADMINISTRATIVE QUALITY PROBLEMS)	JEDEC standard No. 671 (JESD671)	See standards agency
e	PRODUCT DISCONTINUANCE	JEDEC standard No. 48 (JESD48)	See standards agency
f	REQUIREMENTS FOR HANDLING ELECTROSTATIC-DISCHARGE-SENSITIVE (ESDS)DEVICES	JEDEC standard No. 625 (JESD625)	See standards agency
g	SOLDERABILITY TESTS FOR COMPONENT LEADS, TERMINATIONS, LUGS, TERMINALS AND WIRES	IPC/EIA J-STD-002	See standards agency
h	SOLDERABILITY TESTS FOR PRINTED BOARDS	IPC/EIA J-STD-003	See standards agency
i	IPC/JEDEC MOISTURE/REFLOW SENSITIVITY CLASSIFICATION FOR NONHERMETIC SOLID STATE SURFACE MOUNT DEVICE	IPC/JEDEC J-STD-020	See standards agency
j	JOINT INDUSTRY STANDARD CLASSIFICATION OF NON-IC ELECTRONIC COMPONENTS FOR ASSEMBLY PROCESSES	IPC/JEDEC J-STD-075	See standards agency
k	GUIDELINES FOR PACKING AND LABELING OF INTEGRATED CIRCUITS IN UNITCONTAINER PACKING (TUBES, TRAYS, AND TAPE AND REEL)	JEP130	See standards agency
l	FOR THE DEVELOPMENT OF AN ELECTROSTATIC DISCHARGE CONTROL PROGRAM FOR - PROTECTION OF ELECTRICAL AND ELECTRONIC PARTS, ASSEMBLIES AND EQUIPMENT (EXCLUDING ELECTRICALLY INITIATED EXPLOSIVE DEVICES)	ANSI/ESD S20.20	See standards agency
m	ELECTROSTATICS - PART 5-1: PROTECTION OF ELECTRONIC DEVICES FROM ELECTROSTATIC PHENOMENA - GENERAL REQUIREMENTS	IEC61340-5-1	See standards agency

Ref	Celestica Document Name	Document Number	Current Revision
n	Celestica Bar Coding Standard for Procured Production Goods	CELQ-033-STD-51	Rev 8
o	Celestica Packaging and Handling Specification	PK0763-1	
p	Celestica Notification of Products / Process Changes, Discontinued Availability and Product Alerts by Suppliers	DOC#0073917 Legacy CELQ-033-POL-2 Rev 16	Rev0
q	Environmental Requirements for Purchased Components	DOC#0075098 Legacy CELQ-033-POL-7 Rev 10	Rev 3
r	Celestica Conflict Materials Requirements	DOC#DOC0078175 Legacy CELQ-033-POL-63 Rev 0	Rev 4
s	Environmental Requirements for Purchased Chemicals and Consumables	DOC#0075099 Legacy CELQ-033-POL-15 Rev 8	Rev 4

End of Document