

# SPARTON CORPORATION

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## PERFORMANCE EXCELLENCE

*Procurement Standards*

### MEDICAL PRODUCTS

Agile Revision: D

*Sparton Quality Policy:* It is the goal of Sparton Corporation to deliver value through the design, manufacturing and distribution of superior quality products that exceed our customer's needs and expectations, while complying with applicable statutory and regulatory requirements. We strive to excel through continual improvement in all areas of our business environment, and provide our customers with products and services on time, every time.

*Notice:* This standard is subject to periodic review and may be revised at any time; users are cautioned to obtain the latest revision.

## 1.0 Purpose:

Establish clear expectations of quality that act as the procurement standard for any supplier that provide Medical products and/or services to Sparton which may include but not limited to raw materials such as fabricated parts, Printed Circuit Boards, Cables and Wire Harnesses

## 2.0 Scope:

This standard defines Sparton's qualification requirements which shall be applied by the supplier to ensure that medical products and/or services they provide will be compliant with the details of any relevant Purchase Order (PO) or contract.

This standard shall be referenced on each PO placed to qualified suppliers who develop, manufacture and supply materials and/or services that affect Sparton medical products.

## 3.0 Applicable Documents:

ISO 9001-2000:	Quality Management Systems – Requirements
ISO13485:	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
ISO14971:	Medical Device Risk Management
FDA 21 CFR 820:	Good manufacturing Practices Regulations
ANSI/IEEE 1012:	Standards for Software Validation
ANSI/IPC-A-600:	Acceptability of Printed Wiring Boards
ANSI/IPC-A-610:	Acceptability of Electronic Assemblies
ANSI/IPC-A-620:	Requirements & Acceptance for Cable & Wire Harness Assemblies
IPC6012B:	Qualification & Performance Specification for Rigid Printed Boards
C=0:	Zero Acceptance Number Sampling Plans by Nicholas L. Squeglia

## 4.0 Definitions:

Product:	A thing produced by or resulting from a process.
Custom Parts:	Product produced from drawings or specifications and is under revision control.
Services:	Providing or a provider of activities required, as maintenance, repair, etc.
Supplier:	One that agrees to furnish products or perform services at a specified price.
Purchase Order:	Document used to request a supplier to provide something in return for payment providing terms, conditions, specifications and quantities.
Terms and Conditions:	Documented concluded agreement with provisions and/or stipulations
Drawings and Specifications:	Detailed document that provides description or assessment of requirements, dimensions, materials, etc...
Certificate of Compliance:	Document used to state that all applicable Purchase Order, Drawings and, specification requirements have been met.
Non-Conformance:	A failure / defect between supplied products and/or services verses drawings and specifications.
Deviation / Waiver:	Document used to request acceptance to a non-conformance.
Disposition:	Final settlement of a non-conformance, Rework, Use As Is, Repair.
Rework:	A disposition in which it is feasible to correct the non-conformance to meet the original quality or contractual requirements. Where a repetitive problem is identified, a documented instruction shall be created to perform the rework.
Use As Is:	A disposition that does not involve safety, performance, interchangeability or reliability. Such material can be treated as good material.
Repair:	A planned process that returns the material to a predetermined condition, but does not fully meet the original quality or contractual requirements.

## **5.0 Requirements:**

### **5.1 Quality Management System (QMS):**

Sparton's expectations are that a published, implemented and maintained QMS is established, consistent or equivalent to ISO 9001:2000 and preferably to ISO13485. In addition, incorporates any Quality, Terms and Conditions requirements by Sparton. In the case where a formal QMS is not in place, due to the size or lack of complexity of the activities, a survey or audit may be performed to evaluate the operations of the supplier.

#### **5.1.1 Quality Manual:**

When requested by Sparton, the supplier shall submit their quality manual that defines the scope of their QMS which includes details of and justification for any exclusions, reference to the documented procedures established and process interaction.

#### **5.1.2 Procedures and Records:**

The supplier shall make available all procedures and records, related to their QMS, for review. Such documents shall be established and maintained to provide evidence of conformance to Sparton's requirements.

#### **5.1.3 Control:**

The supplier shall ensure that adequate controls are established and maintained throughout the life cycle of Sparton's requirements, and that principles of continuous quality improvements are applied to all processes.

5.1.3.1 A Sparton expectation of suppliers is that all lots of products received have zero non-conformances to its requirements. The use of a statistically sound sampling plan is required.

NOTE: C=0 / Zero Acceptance Number Sampling Plans is preferred.

5.1.3.2 Sparton shall measure the effectiveness of the supplier's quality program by the product receipt history of conformance to requirements within its incoming inspection and manufacturing processes.

#### **5.1.4 On Site Audits and Inspections:**

Sparton reserves the right to evaluate, via on-site facility audits, the effectiveness of the supplier's defined QMS working practices, procedures and associated quality records. Sparton reserves the right of access for our customer and regulatory authorities to all facilities involved in the order and to all applicable records. In addition too, Sparton may perform on-site source inspection for any of its products supplied.

NOTE: In the event that such audits and/or inspections are necessary, reasonable notice will be given to the supplier.

#### **5.1.5 Planning (Custom Parts only):**

Once Sparton has established all necessary product requirements, which includes but not limited to drawings, specifications, manufacturing process information, the supplier shall establish an ongoing control plan that identifies the product realization methods.

5.1.5.1 The control plan may be in the form of a narrative or flow chart with the minimum requirements as follows;

- Sparton part number, description and revision
- Operation / process name or description
- Key characteristic to be controlled
- Inspection stages and evaluation method, i.e., micrometer, caliper, reference to a procedure
- The frequency, sample size and analysis methods
- Reaction plan required if an out-of control condition occurs

## **5.2 Design and Document Control:**

All documentation or property supplied to support the delivery of product is the property of Sparton and is deemed proprietary. This may include but not limited to, Engineering Drawings, Bills of Material, Electronic Files, Software, Assembly / Testing Procedures, Test Fixtures and Specifications.

5.2.1 Any changes the supplier requires, to above documents, must be submitted in writing to Sparton for review and written approval prior to changes taking place.

## **5.3 Conflicting Documents:**

If any conflict exist within Sparton's requirements submitted, purchase order, documentation, drawings, etc... the following order of precedence shall apply:

- Purchase Order.
- Documents referenced on the Purchase Order.
- Sparton's end user (customer) specification/drawings.
- Sparton's specifications/drawings.
- The end item specification such as IPC specifications, when invoked by the customer.

5.3.1 If conflict still persists, supplier shall submit in writing to Sparton, before processing product, for resolution and approvals.

## **5.4 Process Changes:**

The supplier shall notify Sparton in writing for approvals prior to implementation of any changes that directly affect supplied product. This includes but not limited to, QMS, processing, materials, fixtures/tooling, measurement /test equipment, calibration, services and relocation of supplier facility.

## **5.5 First Article (Custom Parts only):**

NOTE: Custom parts consist of, printed wiring boards, fabricated machined parts or cables and programmed parts.

### **5.5.1 Reports and Approvals:**

Unless otherwise specified on the PO a First Article Inspection Report (FAIR) shall be provided to Sparton demonstrating compliance with the requirements of the PO and referenced documents.

5.5.1.1 The FAIR shall be submitted with the first shipment to Sparton for inspection and approvals.

NOTE: Only upon first article approval by Sparton, subsequent shipments will be authorized.

### 5.5.2 Samples:

If First Article approval is a requirement on the PO, supplier shall submit a first piece sample(s) for review, verification and approvals by Sparton. Suppliers shall produce the sample(s) from production tooling. Under special circumstances, prototype samples are permissible. Unless otherwise specified and when applicable, a minimum of three pieces produced from each tool, fixture, cavity or impression shall be submitted.

NOTE: samples shall not waive supplier's obligation to make deliveries in conformance with the requirements, applicable drawings and specifications.

5.5.2.1 Changes to drawing/specification revisions, process tooling or equipment alteration beyond normal maintenance will require supplier to resubmit of a first piece sample.

5.5.2.2 All products submitted as a first piece sample, supplier shall notate as such either on the shipping document, container or bag.

## 5.6 Identification and Traceability:

### 5.6.1 Identification:

Supplier shall identify all packages and container with the part number on Sparton's PO. Other information such PO number; Sparton's customer part number; the heat number, lot or cast number and moisture sensitive level codes may also be required. Suppliers shall tag product parts that are too small for individual markings.

NOTE: Product may be identified by the use of barcode labels if the capability exists.

### 5.6.2 Traceability:

Supplier shall provide traceability on products supplied and shall be traceable to the supplier's inspection and production records.

5.6.2.1 Supplier shall provide traceability of tracing all raw materials, hardware and software back to the original manufacture, used to supply/process product against Sparton's PO and must be adequately determined from the supplier's records.

### 5.6.3 Status:

Each shipment of product shall be accompanied by a Certificate of Compliance (C of C) which includes a statement verifying that the PO and applicable drawings and specification requirements have been met as well as but is not limited to;

- Date of Issue
- Part Number, Description and Revision
- Traceability Number, Serial Number, Batch or Lot Number, Date Code, etc...
- PO Number and Quantity
- Approved Deviations / Waivers

NOTE: The C of C shall be signed by the authorized supplier Quality Representative.

**5.7 Shipment:****5.7.1 Packaging:**

Packaging of all products for delivery shall be in accordance with good commercial practice, unless otherwise specified, and be adequate to assure safe arrival at Sparton. Where applicable, the supplier shall ensure that packaging protects parts from Electro-Static Discharge.

5.7.1.1 In the event that the packaging is deemed to be inadequate by Sparton, the supplier shall make all mutually acceptable changes, at no additional cost, to rectify the packaging to a standard.

5.7.1.2 Parts on reels shall be packaged per the EIA-481 standards. Mixed date codes shall be packaged and identified, separately.

NOTE: Part aging Date codes more than 3 years old are not acceptable unless authorized by Sparton.

**5.7.2 Documents:**

Supplier shall provide the following documentation for each product(s) delivery;

Packing Slip or Waybill: Shall indicate the PO number, Traceability Number or Date Code. If multiple date codes exist, the different date codes need to be clearly identified on packing slip and clearly segregated.

Certificate of Conformance: According to the requirements in 5.6.3

When required: Commercial Invoice, Certificate of Origin, Specific documentation which may include Final Inspection and Test reports.

**5.8 Non-Conformance:****5.8.1 General:**

Sparton may reject any product, individual item or complete lot shipment, delivered that does not conform to established requirements and specifications. Notification will be sent to the supplier of the rejection, rejected items may be returned to the supplier or 100% inspected or reworked at supplier's expense.

**5.8.2 Control:**

Supplier shall operate a comprehensive system for the recording and analysis of all non-conformances (workmanship defects, component failures etc.) occurring during inspection, manufacturing and test of product to be delivered.

**5.8.3 Notification:**

Supplier shall notify Sparton, via the Procurement Buyer, immediately of any potential non-conformances, or latent defects that may be present in the sub-systems and which become apparent subsequent to Sparton accepting delivery.

#### 5.8.4 Segregation:

Supplier shall define and implement procedures for segregation, control and disposition of non-conforming material, including all associated status identification and quarantine arrangements.

#### 5.8.5 Disposition:

The supplier has only the authority to rework any non-conformances identified against the product being delivered.

5.8.5.1 Sparton reserves the right to approve any disposition that is determined to be "Use As Is" or "Repair". The Supplier shall submit a deviation / waiver for any such product for approvals by Sparton prior to delivery.

NOTE: If material has been identified to be scrapped, it shall be rendered unusable.

#### 5.8.6 Warranties:

As outlined in the established Terms and Condition and/or Purchase Order. Sparton's acceptance of any product or services shall not be deemed a waiver of any warranties.

### 6.0 Corrective Action Request:

In the event Sparton identifies non-conforming product, which may be found during the incoming inspection, manufacturing, final inspection processes and/or within the field or laboratory, a formal corrective action request (CAPA) may be issued to the supplier.

#### 6.1 Response:

Sparton's expectations are that the supplier shall submit an initial response within ten working days and a formal written corrective action plan response within thirty working days of issue.

The response shall include:

- Results of supplier's investigation including root cause of non-conformance or defect
- Corrective action steps taken to resolve the non-conformance or defect
- Date corrective actions steps became effective, and
- Status and quantity of all products affected by the non-conformance, including in transit and/or inventory stock/warehouse, etc...

#### 6.2 Approvals:

All submitted corrective action responses are subject to verification and approval by Sparton which shall include monitoring of all future shipments of product to ensure that corrective action taken has produced the intended results.

## **7.0 Records:**

### **7.1 Inspection:**

Supplier shall identify and undertake Inspection of deliverables during product processing, for conformance to Sparton's requirements such as the PO, Drawings, Test Specifications Workmanship Standards, etc...

#### **7.1.1 Raw material certification and verification:**

Supplier shall maintain documentation records that certify the raw material used and testing performed on products.

### **7.2 Retention:**

Unless otherwise specified on the PO, all quality records for medical product(s) ordered shall be retained for a minimum of two years after final delivery to Sparton this includes but are not limited to, inspection and traceability records.

NOTE: Records shall be available whenever requested by Sparton.

7.2.1 In the event supplier does not have the means to maintain and store records for extended periods then such records shall be shipped to Sparton.

## **8.0 Specific Instructions:**

### **8.1 Printed Wiring Boards (PWB):**

Unless otherwise specified on the PO or drawing. PWBs shall meet the performance and qualification requirements of current revision IPC 600 / IPC6011 Class 2.

If there is any special requirement (eg: impedance), proof of compliance will need to be provided. Any special requirement needs to be evaluated and/or tested using coupons, designed per IPC 2221.

In addition, Sparton requires the use of A and B coupons or the preferred A/B coupon, designed per IPC 2221 guidelines, as follows;

- All Bid's, Estimates, RFQ's, Quotes and PO's require IPC 2221 coupon design compliance.
- Destruction of sample product for microsections will not be acceptable.
- All new PO's are to have IPC 2221 compliant coupon designs sent to Purchasing with cc to Commodity Management within seven (7) calendar days of PO issuance.

#### **8.1.1 Test, Final Inspection Reports, solder samples, microsections and coupons:**

Supplier shall include the following for all shipments in a single packet;

- Packing Slip
- Certificate of Compliance
- Solderability test and Electrical test reports
- Cleanliness test report or reference that the boards passed cleanliness requirements on the C of C.
- Copy of traveler or information which contains lot qty, panel qty and number of boards per panel.
- Final Inspection and Microsection report

- All batch microsections, including the identification of microsections to the panel, two virgin coupons (per date code) and two solder samples or solderability coupons.

#### 8.1.2 Serialization code:

Supplier shall provide PWB serialization for all lot quantities delivered to Sparton.

#### 8.1.3 Measling:

Measling shall be addressed as Crazing (per section 3.3.2.2 of IPC 6012B). If PWBs show indications of measling, the supplier shall send evidence that the imperfection does not propagate as a result of thermal testing that replicates future assembly processes.

#### 8.1.4 Edges:

Unless otherwise specified, all PWB edges shall be flush cut/routed perpendicular to the surface of the board.

#### 8.1.5 Electrical Testing:

Unless specifically waived in writing, all PWBs shall be electrically tested regardless of layer count.

8.1.5.1 A certification of test shall be provided with each date-coded lot shipment of PWBs that states the method used to test, quantity tested and passed. A test coverage report explaining any circuits not tested shall be provided with 1<sup>st</sup> piece, part rev change or testing change.

8.1.5.2 Each individual PWB shall be stamped with an “ET” (or applicable marking) to signify that it has passed electrical testing. If space is limited on the board, the supplier shall place the electrical test marking on the panel rail, certifying that all PWBs on that panel have passed electrical testing.

#### 8.1.6 Logo and date code:

Unless otherwise specified, the supplier’s UL registered logo and date code shall be permanently marked on each individual PWB in a location that will not affect the performance of the board.

NOTE: In the case of a RoHS compliant part, the board shall be permanently marked per IPC 1066.

#### 8.1.7 Packaging and Labeling:

Supplier shall package all PWBs in accordance with good commercial practice to prevent scratches, dents or nicks, and maintain flatness.

8.1.7.1 If multiples PWBs are packaged together, each package shall be clearly marked indicating the PWB quantity per package. Vacuum sealing is allowed.

8.1.7.2 The maximum quantity of boards/arrays per package is twenty. The package is to be sealed in such a fashion that it is apparent the original packaging has not been disturbed and the quantity for the package is not questionable.

**8.1.8 Panelization:**

Supplier shall utilize the Sparton created and approved panel array drawing/file.

**8.1.9 Solder:**

Unless otherwise specified the supplier shall not use lead-free solder.

**8.1.10 Solderability requirements:**

For each lot of PCBs delivered, the supplier shall furnish a minimum of two coupons, scrap boards, or extra boards to be used for solderability testing.

8.1.10.1 The supplier shall perform solderability testing in accordance to applicable standards for the class of board being produced and certify such processing on the certificate of compliance.

**8.1.11 X-outs:**

Non-functional boards or “X-OUTS” are prohibited, unless a written deviation is provided by Sparton. When allowed, X-OUTS will be limited to a maximum number per array and a maximum percentage of each purchase Order, line item, and shipment.

**8.1.12 First Article Inspection Report:**

In accordance to section 5.5.2

***Release Control***

	<b>Name</b>	<b>Title</b>	<b>Signature</b>	<b>Date</b>
<b>Originator:</b>	Steve Darmanin	Performance excellence Engineer		03/29/07
<b>Verified By:</b>	Linda Munsey	Corp VP Performance Excellence		03/29/07
<b>Approved:</b>	Linda Munsey	Corp VP Performance Excellence		03/29/07

***Revision History***

<b>Rev.</b>	<b>Change Description</b>	<b>Effective Date</b>
A	Initial Release	03/29/07
B	Updated sec: 5.1, 5.4.1 & 6.1 to reflect Sparton’s expectations and action that may be performed	05/14/07
C	Updated sec: 8.1 to reflect Sparton’s PWB IPC 2221 coupon expectations and supplier actions	08/06/07
D	Updated sec: 8.1 to reflect PWB proof of compliance for special requirements and sec: 8.1.5.1. adding test coverage report requirements	12/01/07