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**Supplier Quality Requirements for Purchased Materials or Service**

**1.0 Scope.** This supplier quality requirements documents defines the terms and conditions relating to the quality of materials or Services supplied to Sanmina that are used in Product (defined as products manufactured and sold by Sanmina) or in the production of Product. The requirements herein apply to all Supplier(s) and their sub-tier Suppliers of materials and Services provided to any Sanmina operation. Supplier shall supply materials and/or Services in compliance with the terms stated herein. No deviation or exceptions apply unless mutually agreed upon in writing with an authorized Sanmina representative. It is Supplier's responsibility to review and fully understand the requirements herein before accepting a Sanmina purchase order. In some cases, Supplier will be required to comply with additional Sanmina requirements that may not be covered specifically in this document or that may differ from the requirements referenced herein. In these cases Sanmina will communicate and document the mutual agreement of said requirements utilizing Sanmina form QAF-0069-C.

**2.0 Order of Precedence (with respect to Quality Requirements only)**

1. Purchase Order
2. Engineering drawings
3. Engineering and material specifications
4. QAF-0069-C "Acknowledgement of Supplementary Supplier Quality Requirements for Purchased Materials or Services"
5. Sanmina Master Supply Agreement (if any) - Note: the terms of the Master Supply Agreement will take precedence over only the pre-printed terms contained on each Purchase Order.
6. QAF-0082-C "Supplier Quality Agreement for Purchased Materials or Services"
7. QAR-0001-C "Supplier Quality Requirements for Purchased Materials or Services"

**3.0 General Requirements**

- 3.01 Unless otherwise specified and approved by Sanmina, Supplier is required to have an applied Quality Management System (QMS) in place that is operated in accordance with and accredited by a third party certification body to the current version of the standard such as ISO 9001, TL 9000, IATF 16949, ISO 13485, or AS 9100. Accredited certification is to be furnished to Sanmina upon request.
- 3.02 Unless specified otherwise and where applicable, Supplier shall be in compliance with the latest revision of applicable standards including but not limited to JEDEC, IPC, ANSI, and SAE.
- 3.03 Supplier shall acknowledge and implement the [RBA \(Responsible Business Alliance\) Code of Conduct](#).
- 3.04 Upon request, Supplier shall provide all appropriate product certifications including all applicable safety, regulatory, and operating systems certifications at Supplier's sole cost and expense.
- 3.05 Evidence of certification to the applied QMS and successful completion of surveillance audits shall be supplied to Sanmina upon request.
- 3.06 Sanmina is committed to achieving third party registration to ISO 14001, the internal standard for environmental management systems in its worldwide manufacturing operations. The goal is to provide Sanmina's Product(s) that are environmentally sound throughout their life cycles. Supplier shall operate in an environmentally responsible manner. Sanmina encourages Supplier to scrutinize its manufacturing processes, identify potential hazards, and use preventive measures to reduce or eliminate potential hazards. All waste material that is generated is to be disposed of in compliance with applicable laws.
- 3.07 Supplier shall have a disaster recovery and business contingency plan in place that minimizes the risk to Sanmina in the event of a natural disaster, labor dispute, or other disturbances in the supply chain. Evidence of the process shall be made available for review upon request.
- 3.08 Supplier shall improve its processes, systems, and performance and sustain both internal and external quality levels of its Material (or Service) using improvement techniques such as six-sigma, lean manufacturing, and/or other techniques consistent with that of the industry.
- 3.09 Material shall comply with specified Sanmina specifications or, if not specified otherwise by Sanmina, with Supplier's specifications effective at the time of receipt of Sanmina purchase order.
- 3.10 Material manufactured date codes of supplied Material shall not exceed 24 months at the time of Material receipt by Sanmina unless agreed upon in writing prior to purchase order release. In some cases commodities will have shorter shelf life requirements and should be specified per the industry standard



- guidance for that commodity. Material shall have a minimum of 6 months remaining on material before date code expiration. Sanmina requirements may also dictate shorter shelf life requirements and will be communicated to Supplier at the time of PO release of those exceptions.
- 3.11 Supplier shall maintain a first in, first out (“FIFO”) inventory control system to ensure that non-conforming Material or prior Product versions or down-rev Product is not inadvertently shipped to Sanmina.
  - 3.12 Supplier shall permit Sanmina and/or its representatives, consultants, customers, or regulatory authorities to enter Supplier’s facilities upon 24 hours notice, except for emergencies where there shall be no notice period at reasonable times to inspect and/or audit such facilities and QMS including records, and any goods, inventories, machinery and equipment, or other items or processes used to manufacture Sanmina Product as it relates to Supplier’s performance to this document.
  - 3.13 Supplier will ensure that Sanmina has the same rights of access with prior notice to any subcontractors of Supplier who are involved in the supply of the products for the purpose of carrying out an audit.
  - 3.14 Supplier shall provide written responses and summaries of actions as a result of audits, corrective action requests, or escalations raised by Sanmina.
  - 3.15 It is Supplier’s responsibility to install any additional processes, tests, or methods in order to fulfill customer requirements.
  - 3.16 Supplier shall maintain and execute internal audits of its operation to insure compliance with written processes, procedures, standards, and agreements.
  - 3.17 Sanmina reserves the right to perform periodic Supplier performance reviews; measuring and providing feedback to Supplier in terms of quality, performance, delivery, cost, responsiveness, and communication. These reviews shall be performed as part of continuous improvement strategies. Supplier is expected to participate in these reviews, in scheduled quality meetings and when necessary provide corrective action plans to improve performance, as required and at its expense.
  - 3.18 Supplier Certification:
    - 3.18.01 Supplier acknowledges that certification may require an audit by Sanmina to assess Supplier’s capability to provide Material(s) or Service(s). Certification audits may be conducted without Sanmina visiting Supplier’s site; however, Sanmina reserves the right to require an onsite audit before providing a certification.
    - 3.18.02 Certification is contingent upon Supplier performance and Sanmina reserves the right to change the certification at any time.
  - 3.19 Changes to Supplier’s quality management system or any significant organizational changes shall be communicated to Sanmina immediately.
  - 3.20 Ensure all employees are aware of their contribution to product and service conformity, their contribution to product safety and the importance of ethical behavior.
  - 3.21 The Supplier shall maintain records which show that the Material compliance with the part specification for either a minimum of five (5) years from date of manufacture or as stated on purchase order whichever is longer.

#### **4.0 Shipping, Packaging, and Labeling Requirements**

- 4.01 For Material that is to be imported into the United States of America, Supplier shall comply with all applicable recommendations or requirements of the Bureau of Customs and Border Protection’s Customers-Trade Partnership Against Terrorism (“[C-TPAT](#)”) initiative. Supplier, upon request shall provide evidence of compliance with the C-TPAT initiative.
- 4.02 All electro-static sensitive devices (ESD) shall be properly packaged to provide protection from electrostatic discharge and in accordance with JEDEC Standard [JESD625](#) latest revision. All ESD sensitive products shall be clearly identified with an ESD warning on each tray, tube, or tope and reel within the shipment.
- 4.03 Material packaging shall not negatively influence Material quality or include any impurities.
- 4.04 Moisture Sensitive Devices as identified by Supplier shall be labeled and packaged per the following:
  - 4.04.01 All Product shall be packaged in an ESD Moisture Barrier Bag (MBB)
  - 4.04.02 Each MBB shall be labeled per Sanmina labeling requirements as indicated below:
    - Each MBB shall be labeled in compliance to JEDEC standard [JEP-113-B](#) and at a minimum include moisture level, original seal date, and re-baking requirements.



- Humidity Indicator Card (HIC) shall be inserted in each MBB indicating device moisture exposure.
- 4.04.03 All moisture sensitive devices shall comply to JEDEC standards [J-STD-033](#) and [J-STD-020](#) latest revision.
- 4.05 Material supplied in tape and reel or tray shall comply with EIA industry standard specifications to ensure proper use in automatic component placement machines.
- 4.06 All products shall, where possible, be labeled per QAR-0069-C Supplier Traceability Requirements for Purchased Material
- 4.07 All product packing slips shall contain RoHS compliancy statement which shall be attached to the hardcopy as an attachment in accordance with [RoHS-F004](#) specifications.

### 5.0 Quality Acceptance Requirements:

- 5.01 Sanmina and Supplier's goal is to achieve and maintain a zero defect level for Incoming Quality Level (IQL). IQL measured in parts per million (PPM) is an ongoing measurement reviewed regularly by Sanmina. If deemed appropriate by Sanmina, mutually agreed upon interim targets shall be defined and communicated to Supplier in order to achieve the zero defect target.
- 5.02 Supplier shall use statistical process controls and a supporting process capability analysis to achieve continuous quality improvement and failure rate reductions. Supplier shall, upon request, provide Sanmina with evidence of such process controls and capabilities, including all supporting documentation.
- 5.03 Sanmina may define the method used in reporting quality goals and the means of expressing the results such as DPPM (defective parts per million) or percentages.
- 5.04 Failure to meet quality targets (with a zero defect approach) as defined by Sanmina over a reasonable and sustained period of time will require Supplier's participation in a quality improvement program as defined by Sanmina. Upon request, Supplier shall furnish quality control plans as agreed to by Sanmina.
- 5.05 Supplier shall maintain and make available upon request outgoing quality inspection, reliability records, and applicable data as defined within this document for a minimum of three years from the date of goods shipment.
- 5.06 Failure by Supplier to drive strategies to achieve zero defect targets may result in the removal of Supplier from the Approve Supplier List.
- 5.07 Supplier shall provide traceability by either lot or date code or where appropriate serial number for purpose of tracing any suspect shipment containing problems.
- 5.08 Supplier shall add a certificate of conformance for each shipment which shall include as a minimum the following items:
  - General information as mentioned in Section 4 (Shipping, Packaging, and Labeling Requirements).
  - Applied tests and the results required by the Purchase Order.

### 6.0 Product Change and Discontinuance Notification

- 6.01 Supplier shall notify Sanmina of all proposed changes that impact the form, fit, function, quality, reliability or status of the Material with regard to environmental legislation such as (by way of example and not limitation) the EU Directive 2002/95/EC on the restriction of the use of certain hazardous substances (collectively all environmental legislation to be referred to herein as "ROHS"). Notification shall be provided via an engineering and/or process change request. Changes affecting a significant amount of parts defined as greater than fifteen part numbers shall be accompanied with an Excel file listing those affected part numbers. All Supplier notifications shall be sent to Sanmina via email to the following Sanmina address: [pcn.eol@sanmina.com](mailto:pcn.eol@sanmina.com). The types of changes, as an example, requiring notification include, but are not limited to:
  - Changes in components (die shrink, etc.)
  - Reduced inspection and/or testing
  - Manufacture site changes
  - Deviations from the MT&Q plan
  - Changes in packing, shipping and labeling of Product or containers
  - Product discontinuance



- Changes in Supplier or Manufacturer part number or name
  - Changes to software or firmware
- 6.02 Supplier, at a minimum, will provide ninety days prior written notice before any change implementation to afford Sanmina the means of determining approval for such changes that ultimately affect Sanmina's end customer.
- 6.03 Supplier shall provide written notice of planned product discontinuation per JEDEC standard [J-STD-048](#) and specifically in accordance with the following timeframes:
- 6 months minimum from the notice for last order dates.
  - 12 months minimum from any discontinuation to manufacture material or from final shipments whichever is a greater period of time.
- 6.04 Supplier shall maintain internal documentation for all ECNs and ECOs for a period of no less than three (3) years (or greater as requested by Sanmina) for commercially used Product.
- 6.05 Where applicable, Supplier shall continue to provide the Product under ECO control including hardware level, firmware version, BIOS version, programmable devices versions, driver version, application version, factory utilities, user/product documentation and diagnostics support that have been qualified by Sanmina until such time as Sanmina qualifies a later version at Sanmina's discretion. In the event of the discovery of a high severity issue in Supplier's Material, at Sanmina's discretion, Supplier shall provide the currently-qualified Product revision with only the specific issue fix and re-certify the fixed product on an emergency basis to minimize the re-qualification effort and response time to correct the problem in the field and/or at the manufacturing facility.
- 6.06 Where applicable, Supplier shall provide Product revisions in support of subsequent standards revisions, operating system updates, and versions including support packs, service releases, and full releases of operating systems in the same family of operating systems as previously supported. This shall include (by way of example and not limitation) all required Product modifications of hardware, BIOS, firmware, programmable devices, drivers, utilities, and applications.
- 6.07 Sanmina has the right to reject any and all intended changes required by Supplier.
- 6.08 Supplier may be required to cover any re-qualification costs at Sanmina or customer site as a result of product changes or product obsolescence initiated by Supplier.
- 6.09 Supplier shall maintain procedures for change notification to Sanmina which are in accordance with this agreement.

## **7.0 Product Quality Notification**

- 7.01 Where Supplier suspects that non-conforming Product may have been shipped to Sanmina, Supplier shall immediately provide written notification to the Sanmina Global Supplier Manager and the buyer that placed the purchase order for the Product.
- 7.02 When Supplier identifies non-conforming Product prior to shipment and wishes to obtain concession or deviation permission for its use, release or acceptance, Supplier shall immediately provide written request to the buyer that placed the purchase order for the Product and obtain Sanmina's final disposition of the non-conforming product applicable to that purchase order.

## **8.0 Expectations When Failures Occur - Failure Analysis and Correction Action**

- 8.01 Supplier shall have a written corrective action procedure in place that responds to complaints received from any Sanmina operation. To assure timely resolution of non-conformance issues, Supplier shall apply appropriate problem-solving techniques to identify root causes and implement permanent corrections. The supplier is required to utilize appropriate methods such as PDCA-FTA or equivalent in order to develop appropriate problem analysis. In addition, Supplier shall use statistical methods where applicable to verify that the corrective action implemented has corrected the problem and the process is in control and continues to produce material that is within specifications.



- 8.02 When a non-conformance is identified, Sanmina will request a thorough, documented root cause / corrective action plan be put in place. Sanmina will notify Supplier of the non-conformance via Sanmina Supplier Corrective Action Request (SCAR). In compliance to JEDEC standard [JESD671](#) latest revision, Supplier is expected to address the following when a SCAR is issued for resolution:
- Initial Problem Definition and Verification
  - Containment Action
  - Defect Verification
  - Definition and Verification of the Root Cause
  - Permanent Corrective Action
  - Corrective Action Verification
- 8.03 The timeframe of the response for the corrective action shall be in accordance with Table 1 in [JESD671](#) latest revision or as otherwise reasonably requested by Sanmina. The overall response time line is 9 days for urgent and 23 days for standard.
- 8.04 “Urgent” is typically defined as a non-conformity that is from the field, poses a safety threat, or causes line stops or stop-ships. However, Sanmina may use its reasonable discretion to identify any issue as an urgent issue. Urgent or standard priorities will be communicated in the formal SCAR to Supplier at the time of issuance.
- 8.05 Supplier is expected to provide support as required by Sanmina including but not limited to on-site representation for failure analysis, to assist in the isolation, diagnosis, and resolution of high severity issues in the field, factory, or development facility, and new Product introduction support.
- 8.06 In the event that nonconforming Material is discovered at any state in the process or in the field Supplier will assume responsibility for the costs incurred by Sanmina and/or its customers as a result of the non-conformance. These costs may include but are not limited to:
- Testing, inspection, and sorting as required
  - Process changes which become necessary in order to remedy nonconformity
  - Recall costs
  - Travel incurred
  - Cost of Product(s) or additional Material impacted by the non-conformity
  - Support costs that are directly related to the resolution of the non-conformity
  - Any external analysis
  - Any additional services incurred by Sanmina to the customer
- 8.07 If Sanmina rejects any goods as non-conforming, Sanmina may, at its option, (a) reduce the quantities of goods ordered under this document by the quantity of non-conforming goods, (b) require Supplier to replace the non-conforming goods, and/or (c) exercise any other applicable rights or remedies Sanmina may have.
- 8.08 Sanmina is not obliged to carry out a more detailed examination upon arrival. However, if defects are noticed during the initial examination, Supplier is to be informed of them immediately and Supplier waives any right to reject delayed notification of their deficiencies.
- 8.09 Supplier is required to furnish a Return Material Authorization (“RMA”) for the return of non-conforming Product within 48 hours of the request. For issues requiring correcting action Supplier is required to provide an RMA within 24 hours of the request. Supplier is also required to provide details on the actions of containment within this 24 hour period.
- 8.10 Supplier will bear all risk of loss with respect to all non-conforming Materials and will promptly pay or reimburse all costs incurred by Sanmina to return, store or dispose any non-conforming Materials. Sanmina’s payment for any non-conforming Materials will not constitute acceptance by Supplier, limit or impair Sanmina’s right to exercise any rights or remedies, or relieve Supplier of its responsibilities for the non-conforming Materials.
- 8.11 Material identified as non-conforming Material shall not be reworked and sold to Sanmina as new Material unless prior written authorization has been granted.
- 8.12 Supplier shall perform Failure Analysis on all returned non-conforming Material and when requested shall provide results to Sanmina. Supplier shall collect the data resulting from returned non-conforming Material failure analyses and evaluate trends and recurrences for continuous improvement.

**9.0 Quality Recording Keeping**

- 9.01 Supplier will comply with obligations to keep quality records in accordance with the medical, automotive, or general standards as applicable or as mutually agreed upon and in no case less than 3 years.
- 9.02 Quality records shall be kept and maintained to provide evidence of Product conformance to Supplier's quality management system.
- 9.03 For Suppliers providing Material used on medical Products, records shall be retained for a period of time equivalent to the design and expected life of the device, but in no case less than 3 years from the date of release for commercial distribution by the manufacturer.

**10.0 ROHS / WEEE Compliance**

- 10.01 Supplier shall comply with Sanmina's RoHS/WEEE Specifications and Requirements as set out in Sanmina's [RoHS-F004](#) document.

**11.0 Counterfeit component avoidance**

- 11.01 "Franchised distributor" means a distributor whom a manufacturer has authorized to distribute its product lines as defined in IDEA-STD-1010. Franchised distributors are expected to have contracts with the manufacturer to exclusively provide inventory to the original component manufacturer.
- 11.02 "Independent distributor" means a distributor that purchases excess inventories from end users with the intention to sell and redistribute onto the market that do not have limiting contractual agreements or obligations with the original component manufacturer as defined in IDEA-STD-1010.
- 11.03 Independent distributors are required to provide verification of authenticity in the form of a certificate of compliance that includes the original manufacturer's name and batch identification for the item(s) such as date codes, lot codes, serializations, or other batch identifications for each item shipped and shall include the following:
  - General information as mentioned in Section 4 (Shipping, Packaging, and Labeling Requirements).
  - Applied tests and the results.
  - Shall state a known chain of custody for the material originating from the original component manufacture or evidence of verification of part compliance utilizing methods defined in section 11.04
  - Shall state the part meets the conditions of new as defined in IDEA-STD-1010 or has included an approved deviation to included parts meeting the conditions of unused as defined in IDEA-STD-1010.
- 11.04 Independent distributors shall maintain a counterfeit electronic part detection and avoidance system including risk-based policies and procedures that address, at a minimum, the following areas:
  - 11.04.01 Personnel training. Preference for inspectors to be certified to IDEA-ICE-3000 or CCCI-102.
    - 11.04.02 The inspection and testing of electronic parts, including criteria for acceptance and rejection. Tests shall be performed in accordance with AS6171 and inspections shall be performed per IDEA-STD-1010. Selection of tests and inspections shall be based on minimizing risk to the Sanmina. Determination of risk shall be based on the assessed probability of receiving a counterfeit electronic part; the probability that the inspection or test selected will detect a counterfeit electronic part; and the potential negative consequences of a counterfeit electronic part being installed (e.g., human safety, product impact).
    - 11.04.03 Processes to abolish counterfeit parts proliferation including quarantining and disposal of counterfeit material.
    - 11.04.04 Processes that enable establishing a chain of custody for the electronic parts from the OCM to the independent distributor. If the independent distributor cannot establish the chain of custody from the OCM for a specific part then apply a risk-based inspection or testing, to authenticate the electronic part, in accordance with existing applicable industry standards, and maintain documentation of the chain of custody, or inspection and testing applied to authenticate the part when traceability cannot be established and make such documentation available to the Sanmina upon request.



- 11.04.05 Supplier shall immediately notify Sanmina at [quality.portal+counterfeit@sanmina.com](mailto:quality.portal+counterfeit@sanmina.com) and the buyer on the purchase order with the pertinent facts if Supplier becomes aware of or suspects that items delivered for the Purchase Order are, or contain, suspect or confirmed counterfeit items. This includes but is not limited to the affected purchase orders numbers, all information on purchase order that identifies the affected good including the original component manufacture, part number and lot code and the evidence of suspected counterfeit.
- 11.04.06 Supplier and supplier's subcontractors that are allowed access to the US Government Industry Data Exchange Program (GIDEP) shall participate in monitoring GIDEP reports and Supplier shall act on GIDEP reports that affect product delivered to Sanmina.
- 11.04.07 The Supplier and/or the supplier's subcontractors shall cooperate in good faith with any investigation conducted by Sanmina. Sanmina shall not be required to return the good during the investigation process and thereafter if not found to be authentic. Sanmina shall not be liable for payment to Supplier of the price of any Suspect Counterfeit Items until determined to be authentic. If Sanmina determines in its sole discretion that there is credible evidence that a good delivered under this Purchase Order constitutes a Counterfeit Item or Suspect Counterfeit Item, Supplier, or its subcontractor, shall, if directed by Sanmina to do so, issue a GIDEP alert. Sanmina reserves its right to issue its own GIDEP alert if Buyer concludes, in its sole estimation, that a good is a Counterfeit Item or Suspect Counterfeit Item. Sanmina recommends that suspect counterfeit parts also be reported to ERAI.
- 11.05 There shall be an effective system for the legal disposition of counterfeit components and control of non-conforming product.
- 11.06 Independent distributors shall perform component inspection per IDEA-STD-1010.

**12.0 Conflict minerals avoidance**

- 12.01 Supplier shall comply with Sanmina's Conflict Minerals Specifications and Requirements as set out in Sanmina's [Supplier Conflict Minerals Requirements](#) document.
- Conduct appropriate conflict minerals due diligence within your supply chain, using the OECD Conflict Minerals Due Diligence Guidelines as a framework.
  - Identify and take actions to mitigate any risks identified as part of this due diligence.
  - Report the results of your due diligence to Sanmina using the EICC/GeSI Conflict Minerals reporting template as requested by Sanmina.
  - Provide an updated template if there are any material changes to the results of your due diligence.

**Addendum A****Automotive Addendum to the Supplier Quality Requirements  
For Purchased Materials or Services Document**

**A-1.0 Scope:** The following requirements are for Suppliers that are supplying Materials or Services intended for use in automotive product. This addendum supersedes any requirements called out in the general document which may be in conflict.

**A-2.0 Automotive Requirements:**

- A-2.01 Supplier shall at a minimum, be certified to ISO 9001 and have a willingness to develop a system in compliance to IATF 16949.
- A-2.02 Unless otherwise agreed upon in advance, Supplier shall be in compliance and have processes that are compliant to the following:
- Advanced product Quality Planning - ("APQP") (AIAG / QS 9000 / VDA 4.3)
  - Production Part Approval Process - ("PPAP") (AIAG Manual / VDA 2) - or as requested by Sanmina
  - International Material Data System - ("IMDS")
  - Quality Management Planning
  - Management System Audit (QS 9000, IATF 16949)
  - Automotive Industry Action Group - ("AIAG") - AIAG Manuals
  - Zero Defect Approach
  - Applicable standards including but not limited to JEDEC, IPC, ANSI, and SAE.
- A-2.03 Packaging instructions shall be included in the PPAP.
- A-2.04 The supplier shall add a certificate of conformance to each shipment which shall include in minimum the following items:
- General information as mentioned in the Shipping, Packaging, and Labeling Requirements section.
  - Applied tests and the results.
  - Information that the material is still in accordance with the data sheet and the latest version of the PPAP.
- A-2.05 Machine and Process capabilities should be minimum Cmk  $\geq 2.0$  / Cpk  $\geq 2.0$  / Ppk  $\geq 1.67$ . If lower, it is expected that Supplier will put additional inspections in place.
- A-2.06 Supplier shall maintain and make available upon request outgoing quality inspection, reliability records, and applicable data as defined within this document for a minimum of fifteen (15) years after product shipment.
- A-2.07 The corrective action timeframe shall be in accordance with corrective actions and shall be considered "urgent" as referenced in Table 1 in [JESD671](#) latest revision or as otherwise reasonably requested by Sanmina.
- A-2.08 Supplier will bear all risk of loss and costs with respect to all non-conforming Materials and will promptly pay or reimburse all costs incurred by Sanmina to return, store, or dispose any non-conforming materials. Sanmina's payment for any non-conforming Materials will not constitute acceptance by Sanmina, nor shall acceptance limit or impair Sanmina's right to exercise any rights or remedies, or relieve Supplier of its responsibilities for the non-conforming Materials.
- A-2.09 Suppliers shall provide and maintain a quality improvement plan on a quarterly basis or as otherwise requested by Sanmina.
- A-2.10 Targeted PPM values aimed at achieving the zero defect strategy may be communicated to Supplier. It is intended that Supplier will strive to attain these set targets communicated to Supplier by Sanmina. Failure to meet set targets will require a formal corrective action plan.
- A-2.11 Supplier shall implement and maintain a process for software quality assurance for product-related software, or products with embedded software.
- A-2.12 Supplier shall document and retain software development capability self-assessment information.





**Addendum B**

**Medical Division Addendum to the Supplier Quality Requirements for Purchased Materials or Services**

**B-1.0 Scope:** The following requirements are for Suppliers that are supplying Materials or Services intended for use in medical product. This addendum supersedes any requirements called out in the general document which may be in conflict.

**B-2.0 Medical Requirements:** In order for Sanmina to furnish devices that are safe, effective and in compliance with the Federal Food, Drug and Cosmetic Act.

B-2.01 In compliance with FDA Regulations 21 CFR Part 820.50, Purchasing Controls, Supplier shall comply with section 6.0 in the general document.

- At a minimum, change notification information shall consist of change description, proposed change date, affected part number(s), contact information, reason for change and method of identification.
- Associated records shall be maintained for a minimum of 15 years.

B-2.02 In compliance with FDA Regulations 21 CFR Part 820.60, Identification, Supplier shall comply with section 3.0 in the general document.

B-2.03 In compliance with FDA Regulations 21 CFR Part 820.65, Traceability, Supplier shall comply with 5.07 and 4.06.

- Each package of material furnished shall contain Material with the same lot or date code and purchase order unless prior written authorization has been granted. In these cases Sanmina will communicate and document the mutual agreement of said requirements utilizing Sanmina form QAF-0069-C.

**B-3.0 Compliance Failures:**

B-3.1 Failure to comply with the above Medical requirements renders the resulting devices “adulterated” and subject (along with the responsible party) to regulatory action.

\_\_\_\_\_  
Legal Supplier Name

\_\_\_\_\_  
Supplier Representative

\_\_\_\_\_  
Date

\_\_\_\_\_  
Title

\_\_\_\_\_  
Sanmina Representative

\_\_\_\_\_  
Date

\_\_\_\_\_  
Title