Global Quality Management System Supplement for the Medical Device Industry Model, ISO 13485:2003

1. SCOPE

1.1. Content

This specification defines the medical device industry quality management system requirements in accordance with ISO 13485: 2003, Medical devices – Quality management systems – Requirements for regulatory purposes. In addition, this document is a supplement to Quality Specification, TEC-1000 in providing criteria for compliance to medical device industry requirements.

Requirements of ISO 13485:2003, paragraph 7, that are not applicable to the medical device products for which this Quality Management System is applied, are noted herein with the term “EXCLUSION” under the description of the non-applicable requirement. The exclusions are accompanied with a justification statement.

Alignment to Quality Specification TEC-1000 is achieved through the ISO 9001: 2008, paragraph tables which address the differences between ISO 13485:2003 and ISO 9001:2000 as illustrated in ISO 13485:2003, Annex B.

1.2. Application

This specification applies to all Business Units of Tyco Electronics. In recognition of the varying organizational structures and needs, Business Units may develop and use supporting specifications and/or procedures. However, such supporting documentation shall not conflict with or supersede this specification.

1.3. Process Interactions

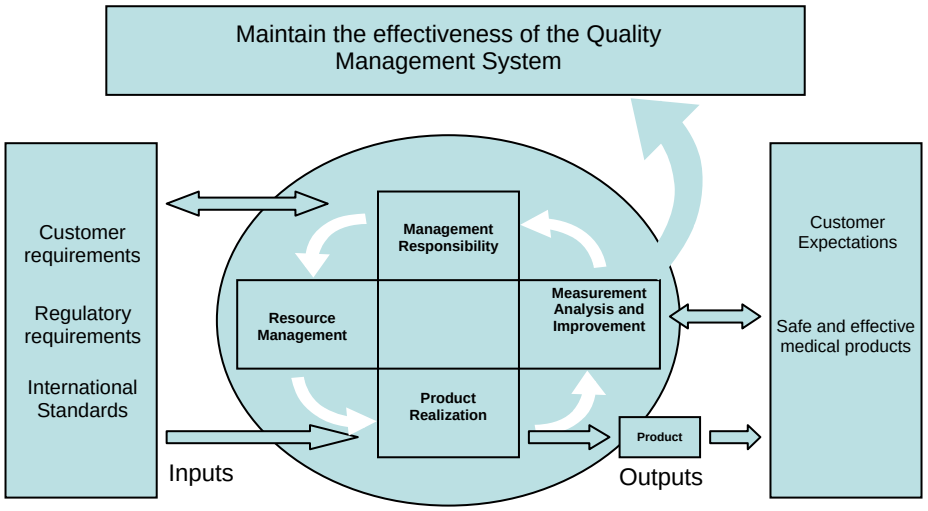

Figure 1

2. APPLICABLE DOCUMENTS

The following documents constitute a part of this specification to the extent specified herein. Unless otherwise specified, the latest edition of the document applies.

2.1. Specifications

A.	TEC-1000	Tyco Electronics Global Quality Management System
B.	TEC-1003	Supplier Performance Reporting and Continual Improvement Process
C.	TEC-1005	Tyco Electronics Total Quality Management Requirements for Suppliers
D.	TEC-1006	Approval of Suppliers
E.	TEC-1017	Global Quality Management System Cross-Reference for Policies, Specifications, and Standards

2.2. Industry Standards

A.	ISO 13485:2003	Medical devices – Quality management systems – Requirements for regulatory purposes
B.	ISO 9001:2008	Quality management systems - Requirements
C.	ISO 9001:2000	Quality management systems – Requirements
D.	ISO 9004:2000	Quality management systems – Guidelines for performance improvements
E.	ISO 10012:2003	Quality management systems – Guidelines for configuration management
F.	ISO 14971:2007	Medical devices – Application of risk management for medical devices
G.	ISO 19011:2002	Guidelines for quality and/or environmental management systems auditing

2.3. Enterprise Resource Planning (ERP) System

StarTEC Documentation Management (DM.TEC) System

3. DEFINITIONS

Definitions contained in the above mentioned Specifications and Industry Standards are applicable herein.

NOTE *On all subsequent pages, **Bold Text** in the right hand column represents Tyco Electronics commentary.*

4. QUALITY MANAGEMENT SYSTEM (QMS)

TEC-1000		SUPPLEMENTARY ISO 13485: 2003 REQUIREMENTS	
4.1.	**QMS – General Requirements**	4.1.	General Requirements
			The organization shall establish, document, implement and maintain a quality management system and maintain its effectiveness in accordance with the requirements of this International Standard. **The Tyco Electronics model for the quality management system is derived from ISO 9004 and is supplemented by customer and regulatory requirements. Quality system models including ISO 9001, and the telecommunications, automotive, and aerospace industry Standards provide the basic framework for the quality system. ISO 13485: 2003 provides the additional requirements for the medical quality management system. Procedures are documented, implemented, maintained and improved with appropriate feedback from inspection, assessments, and customers to determine system effectiveness. The model is further complimented by the Tyco Electronics Operating Advantage approach to business process improvement.**
4.2.	**Documentation Requirements**		
4.2.1.	**Documentation Requirements – General**	4.2.1.	General
			The quality management system documentation shall include: Any other documentation specified by national or regional regulations. Where this International Standard specifies that a requirement, procedure, activity or special arrangement be “documented”, it shall, in addition, be implemented and maintained. **The quality management system will fulfill all the documentation and implementation requirements of applicable regulatory authorities.** For each type or model of medical device, the organization shall establish and maintain a file either containing or identifying documents defining product specifications and quality management system requirements (see 4.2.3). These documents shall define the complete manufacturing process and, if applicable, installation and servicing. **Product specifications, drawings, and manufacturing process documentation will be established and maintained for each medical device part number.**
4.2.2.	**Quality Manual**	4.2.2.	Quality Manual
			The organization shall establish and maintain a quality manual that includes the scope of the quality management system, including details of and justification for any exclusion and/or non-application. The quality manual shall outline the structure of the documentation used in the quality management system.

TEC-1000		SUPPLEMENTARY ISO 13485: 2003 REQUIREMENTS	
			The Tyco Electronics Global Quality Management Process Manual, TEC-1000, is supported by detailed procedures, specifications, and policies including this global medical device industry manual supplement. In combination, these documents form the foundation of the quality management system which provides a means to ensure that products and services conform to specified requirements. **This addendum defines corporate level exclusions to the ISO 13485: 2003 standard. In addition facilities shall have a facility level medical addendum that further defines the exemptions based on business model.** **A list of supporting documentation is contained in TEC-1017, Quality Management System Cross-Reference.** **Business Units shall further document the specific procedures used by the organization to support the Quality Management System.**
4.2.3. **4.2.3.1.** **4.2.3.2.** **4.2.3.3.**	**Document and Data Control** **Initial Issue** **Changes** **Drawings, Standards, and Specifications**	4.2.3.	Control of Documents
			A documented procedure shall be established to define the controls needed to review and approve documents for adequacy prior to issue. **The documented procedure defining the document control process provides for the timely review, distribution and maintenance of documentation for policies, processes, procedures, or techniques. The process provides for document approval, the use of a unique identifier for each controlled document, a distribution list or an equivalent method for identifying recipients, and change control. This control applies to documents regardless of format or media.** The organization shall ensure that changes to documents are reviewed and approved either by the original approving function or another designated function which has access to pertinent background information upon which to base its decisions. **All Tyco Electronics controlled documents are maintained, released for use, and revised through the StarTEC Documentation Management (DM.TEC) System. This electronic system ensures that changes to documents are reviewed and approved by a designated function with access to all previous history. The system also notifies users of a pending release or change and again when the document is approved for use.** **Business Units shall also control, release and revise locally generated documents in manner that meets the requirements of the standard.**

TEC-1000		SUPPLEMENTARY ISO 13485: 2003 REQUIREMENTS	
			The organization shall define the period for which at least one copy of obsolete controlled documents shall be retained. This period shall ensure that documents to which medical devices have been manufactured and tested are available for at least the lifetime of the medical device as defined by the organization, but not less than the retention period of any resulting record or as specified by relevant regulatory requirements. **Unless otherwise specified by customer requirements or regulation, the controlling function shall retain originals and revisions of all documents in accordance with Tyco Electronics defined requirements.**
4.2.4.	**Control of Quality Records**	4.2.4.	Control of Records
			The organization shall retain the records for a period of time at least equivalent to the lifetime of the medical device as defined by the organization, but not less than two years from the date of product release by the organization or as specified by relevant regulatory requirements. **The Business Unit shall identify, collect, maintain, store, and dispose of quality records as specified by customers and/or regulatory requirements.**

5. MANAGEMENT RESPONSIBILITY

TEC-1000		SUPPLEMENTARY ISO 13485: 2003 REQUIREMENTS	
5.1.	**Management Commitment**	5.1.	Management commitment
			Top management shall provide evidence of its commitment to the development and implementation of the quality management system and maintaining its effectiveness. **NOTE** *For the purposes of this International Standard, statutory requirements are limited to the safety and performance of the medical device only*. **Top management of Tyco Electronics maintains the leadership responsibility for the Quality Management System and the Tyco Electronics Operating Advantage program. This responsibility includes:** • **Ensuring the availability of resources;** • **Establishing and reviewing the quality policy and quality objectives;** • **Conducting management reviews;** • **Implementing continual improvement of the quality management system;** • **Developing breakthrough process improvement initiatives;** • **Communicating the importance of meeting customer, safety and regulatory requirements; and** • **Ensuring regulatory compliance.** **(TEC-1000)** **The Business Unit leaders, including Quality Assurance, Engineering, Operations, Sales and Marketing support and assist top management in these initiatives.**
5.2.	**Customer Focus**	5.2.	Customer Focus
			Top management shall ensure that customer requirements are determined and are met (see 7.2.1 and 8.2.1). **Top management of Tyco Electronics maintains the leadership responsibility for the Quality Management System which includes the determination and compliance to customer, safety, and regulatory requirements.**
5.3.	**Quality Policy**	5.3.	Quality Policy
			Top management shall ensure that the quality policy includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system.

TEC-1000		SUPPLEMENTARY ISO 13485: 2003 REQUIREMENTS	
			It is the goal of Tyco Electronics to continually deliver safe, effective, high-quality products and services, on time, to our customers and internal operations. Processes and controls shall be implemented such that tasks are performed properly the first time, so that products and services meet established agreed to requirements. Quality, customer satisfaction, continual improvement, maintaining effectiveness of our quality management system, and compliance with customer and regulatory requirements are the personal responsibility of every employee. (TEC-1000) **Business units shall establish a compliance plan and compliance metrics relative to the medical device design and manufacturing. Plan and metrics shall be applicable to regulatory and customer requirements.**
5.4. **Planning** **5.4.1.** **Quality Objectives** **5.4.2.** **QMS Planning** **5.5.** **Responsibility, Authority and Communication** **5.5.1.** **Responsibility and Authority** **5.5.2.** **Management Representative** **5.5.3.** **Internal Communication**		5.5.1.	Responsibility and Authority
			Top management shall establish the interrelation of all personnel who manage, perform and verify work affecting quality, and shall ensure the independence and authority necessary to perform these tasks. **NOTE** *National or regional regulation might require the nomination of specific persons as responsible for activities related to monitoring experience from the post-production stage and reporting adverse events (see 8.2.1 and 8.5.1).* **The responsibility, authority, and interrelationship of all personnel and functions who influence product design, quality, processes, preventive and corrective action, or the quality system are defined and communicated through, but not limited to, organizational charts, job or position descriptions, skill requirements, individual performance reviews, documented quality specifications, and the functional responsibilities defined in this document.** **All personnel have the authority to halt nonconforming processes and initiate, recommend, or provide corrective and preventive solutions through designated channels. (TEC-1000)**
		5.5.2.	Management Representative
			Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes ensuring the promotion of awareness of regulatory and customer requirements throughout the organization.

TEC-1000		SUPPLEMENTARY ISO 13485: 2003 REQUIREMENTS	
			Top management of Business Units involved with medical device products and compliance to ISO 13485: 2003 shall appoint a representative who, irrespective of other responsibilities, shall have the responsibility and authority for: • **Ensuring that the requirements of the Quality Management System are established, implemented, and maintained;** • **Ensuring compliance to pertinent industry requirements as agreed upon contractually with customers;** • **Ensuring regulatory compliance;** • **Reporting to senior management on the performance of the quality management system as a basis for continual improvement;** • **Assisting senior management in promoting customer requirements and continual improvement throughout the organization.** • **Ensuring the promotion of awareness of regulatory and customer requirements throughout the organization**
5.6. **5.6.1.** **5.6.2.** **5.6.3.**	**Management Review** **General** **Review Input** **Review Output**	5.6.2.	Review Input
			The input to management review shall include information on new or revised regulatory requirements. **Business Units involved with medical device products and compliance to ISO 13485: 2003 shall include information on new or revised regulatory requirements as an input to management review. In addition, review input shall include:** • **Compliance metrics and status;** • **Training needs relative to medical and regulatory requirements; and** • **Supplier issues relative to medical device products.**
		5.6.3.	Review Output
			The output from the management review shall include any decisions and actions related to improvements needed to maintain the effectiveness of the quality management system and its processes. **The output from the management review shall include any decisions and actions related to:** • **Decisions and actions related to improvement needed to maintain the effectiveness of the quality management system and it's supporting processes;** • **Improvement of product related to customer requirements;** • **Resource needs;** • **Training needs; and** • **Compliance status and action plans.**

6. RESOURCE MANAGEMENT

TEC-1000		SUPPLEMENTARY ISO 13485: 2003 REQUIREMENTS	
6.1.	**Provision of Resources**	6.1.	Provision of Resources
			The organization shall determine and provide the resources needed • To implement the quality management system and to maintain its effectiveness, and • To meet regulatory and customer requirements. **It is the responsibility of Management to ensure that the resources that are essential to the achievement of the organization's objectives, including implementing, maintaining and improving the quality management system, enhancing customer satisfaction, and meeting regulatory requirements are identified during the planning processes.** **Resource requirements are usually planned during the budgeting process and adjusted during the year in response to sales growth, profit plans, capacity constraints, changing customer and/or regulatory requirements, and other internal needs.**
6.2. **6.2.1.** **6.2.2.** **6.2.2.1.** **6.2.2.2.** **6.2.2.3.**	**Human Resources** **General** **Competence, Training and Awareness** **Human Resources Function** **Qualification Training** **Training Effectiveness**	6.2.2.	Competence, Awareness and Training
			NOTE *National and regional regulations might require the organization to establish documented procedures for identifying training needs.* **As mandated by national and/or regional regulations, Management shall determine specific training needs, document the needs as job skills, provide the subject training, and verify the effectiveness of the training.** **Training shall include medical and regulatory awareness specific to the type of products being manufactured.** **The Business Unit shall define training requirements for personnel required to work in a controlled environment. All personnel shall be appropriately training or supervised by a trained person.** **Risk Management activities shall support the establishment and review of training requirements.**
6.3.	**Infrastructure**	6.3.	Infrastructure
			The organization shall establish documented requirements for maintenance activities, including their frequency, when such activities or lack thereof can affect product quality. Records of such maintenance shall be maintained (see 4.2.4).

TEC-1000		SUPPLEMENTARY ISO 13485: 2003 REQUIREMENTS	
			An effective preventive maintenance program shall be developed and implemented at a facility level that identifies key process equipment and information systems as well as, monitoring/measuring devices and provides appropriate resources for equipment maintenance. Maintenance activities are deployed to sustain process capability requirements and product quality requirements. As a minimum, the preventive maintenance program shall identify key process equipment, establish planned maintenance activities and intervals, deploy predictive methods, manage the availability of replacement parts for key manufacturing equipment, and periodically evaluate maintenance activities for program improvement opportunities. (TEC-1000) **Records of maintenance activities shall be retained.**
6.4.	**Work Environment**	6.4.	Work Environment
			The organization shall determine and manage the work environment needed to achieve conformity to product requirements. The following requirements shall apply. • The organization shall establish documented requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could adversely affect the quality of the product (see 7.5.1.2.1). • If work environment conditions can have an adverse effect on product quality, the organization shall establish documented requirements for the work environment conditions and documented procedures or work instructions to monitor and control these work environment conditions (see 7.5.1.2.1). • The organization shall ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are appropriately trained or supervised by a trained person (see 6.2.2.b). • If appropriate, special arrangements shall be established and documented for the control of contaminated or potentially contaminated product in order to prevent contamination of other product, the work environment or personnel (see 7.5.3.1). **Facilities, including controlled environments, workstations, and associated equipment shall be maintained in a state of order, cleanliness, and repair to ensure that they do not adversely affect product quality or personnel performance. All work areas must comply with established safety, regulatory and environmental standards and codes.** **As applicable, the 'cleanliness of product and contamination control' requirements will be recognized, procedurally documented, and implemented.**

7. PRODUCT REALIZATION

TEC-1000		SUPPLEMENTARY ISO 13485: 2003 REQUIREMENTS	
7.1.	**Planning of Product Realization**	7.1.	Planning of Product Realization
7.1.1.	**New Product Introduction**		The organization shall establish documented requirements for risk management throughout product realization. Records arising from risk management shall be maintained (see 4.2). **NOTE 3** *See ISO 14971 for guidance related to risk management.* **Business Units involved with medical device products and compliance to ISO 13485: 2003 shall establish, document and maintain requirements for risk management throughout product realization.** **Design and development principles defined in paragraph 7.3 shall be applied throughout the product realization processes. These principles include process planning, input consideration, reviews by functional representatives, process verification, and process change management.** **Risk management is a management discipline that applies technical and administrative direction to development, production and support during the product life cycle. The requirements for risk management shall be documented. Risk management shall be an integral part of the quality management system. At a minimum, the requirements for risk management shall be documented as part of development, sourcing, product migration, and supplier selection and is considered an output of the management review process. Records resulting from risk management activities such as customer contract acceptance, product development plans, design verifications, supplier selection, etc. shall be maintained in accordance with the corporate records retention schedule.** **ISO 14971, Medical devices – Application of risk management to medical devices, shall be used as guidance for risk management.**
7.1.2.	**Disaster Recovery Planning**		
7.2.	**Customer Related Processes**	7.2.2.	Review of Requirements Related to the Product
7.2.1.	**Determination of Product Related Requirements**		Review of Requirements Related to the Product The organization shall review the requirements related to product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that product requirements are defined and documented.
7.2.2.	**Review of Product Related Requirements**		
7.2.2.1.	**Customer Service**		

TEC-1000		SUPPLEMENTARY ISO 13485: 2003 REQUIREMENTS	
7.2.2.2.	**Customer Specification Review**		**The Customer Service function shall be responsible for:** • **Ensuring adequate definition and documentation of customer requirements;** • **Forwarding to the appropriate functions customer specifications, requests for quotes, contracts, or purchase orders in which the customer is ordering product with nonstandard requirements;** • **Requests for alterations to products and services as specified in the customer documentation.**
7.2.3.	**Customer Communication**	7.2.3.	Customer Communication
			The organization shall determine and implement effective arrangements for communicating with customers in relation to advisory notices (see 8.5.1). **Customer advisory notices shall be issued in accordance with established documented procedures with records of advisory notices maintained.**
7.3.	**Design and Development**	7.3.1.	Design and Development Planning
7.3.1.	**Design and Development Planning**		The organization shall establish documented procedures for design and development. **Documented procedures are established and maintained defining various aspects of product design and development including design objective preparation, design reviews, failure modes and effects analysis, product testing, engineering change control, and design history files.** During the design and development planning, the organization shall determine the review, verification, validation and design transfer activities (see NOTE) that are appropriate at each design and development stage. Planning output shall be documented and updated as appropriate, as the design and development progresses (see 4.2.3). **NOTE** Design transfer activities during the design and development process ensure that design and development outputs are verified as suitable for manufacturing before becoming final production specifications.
7.3.1.1.	**Project Planning**		

TEC-1000		SUPPLEMENTARY ISO 13485: 2003 REQUIREMENTS	
			Project plans shall be prepared by engineering management that identify the responsibility, budgets, staffing and schedules for each design and development activity. The plans shall be updated and communicated to the appropriate individuals as each design evolves. The plans, based on the life cycle model, shall describe or reference the following activities, as applicable: • **Organizational and technical interfaces between different groups (internal and external) shall be identified and the necessary information documented, transmitted, and reviewed;** • **Project roles and responsibilities;** • **Project reporting requirements, including tracking and resolving open issues;** • **Risk management and contingency plans; and** • **Performance, safety, security and other critical requirements.** **Regulatory requirements for product and sourcing:** • **Any project specific training requirements;** • **Usage or licensing rights; and** • **Post project analysis.**
7.3.2. **7.3.2.1.**	**Design and Development Inputs** **Customer Input**	7.3.2.	Design and Development Inputs Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include • Functional, performance and safety requirements, according to the intended use, • Outputs of risk management (see 7.1). These inputs shall be reviewed for adequacy and approved.

TEC-1000		SUPPLEMENTARY ISO 13485: 2003 REQUIREMENTS	
			Design input requirements relating to the product requirements shall be identified, documented, reviewed, and approved by the Business Unit. Records of design input shall be maintained. Design inputs shall consider, but not be limited to: • **Requirements established by the customer input;** • **Functional, performance, and safety requirements;** • **Design constraints;** • **Requirements for certification / agency approvals;** • **Overall fitness for and impact on the customer's application, including, as applicable, installation ease, usability, and maintainability;** • **Outputs of risk management;** • **Supplier capability and input;** • **Performance characteristics such as environmental and usage conditions, including any reliability requirements;** • **Ergonomic characteristics such as ease of handling and ease of use;** • **Installation, configuration, or fit;** • **Industry standards and safety and regulatory requirements;** • **Packaging and marking;** • **Quality / product assurance inspection activities;** • **Verification and validation testing requirements;** • **Application requirements;** • **Manufacturing and procurement requirements; and** • **Analysis of similar product (including competitive product) and process designs, work operations, deviations, quality records, service reports, and customer complaints to detect and eliminate potential causes of nonconforming product.**
7.3.3.	**Design and Development Outputs**	7.3.3.	Design and Development Outputs
			Records of the design and development outputs shall be maintained (see 4.2.2). **NOTE** *Records of design and development outputs can include specifications, manufacturing procedures, engineering drawings, and engineering or research logbooks.*

TEC-1000		SUPPLEMENTARY ISO 13485: 2003 REQUIREMENTS	
			The design output shall be documented and maintaiined and expressed in terms of requirements, calculations and analyses, and shall: • **Meet the design input requirements;** • **Provide the information required for manufacturing the product – including any purchasing information;** • **Define the inspection process including acceptance criteria;** • **Conform to documented industry, safety and regulatory requirements where appropriate;** • **Identify those characteristics of the design that are crucial to the safe and proper functioning of the product;** • **Comply with customer specified definitions and symbols or equivalent on applicable Tyco Electronics documentation; and** • **Result from a process that makes appropriate use of the Basic and Advanced Quality Tools, such as Design of Experiments (DOE), Failure Mode and Effects Analysis (FMEA); Statistical Tolerance Analysis, etc.**
7.3.4.	**Design and Development Review**	7.3.4.	Design and Development Review
			Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed, as well as other specialist personnel (see 5.5.1 and 6.2.1). **All product designs shall be analyzed via a formal design review process. Design review activities shall be held at key times during the development cycle and include representatives from all pertient functions. These representative shall include any needed specialists. Design reviews for finished devices or device accessories shall include applicable regulatory representation.** **The purpose of design reviews shall be to determine if the product design has the ability to meet established requirements, identify problems, and propose necessary actions. Design review activities shall be documented and administered in accordance with the specification for design review. As determined, the design review process may provide the means for design project authorization. Records of design review activities and resulting actions shall be maintained.**

TEC-1000		SUPPLEMENTARY ISO 13485: 2003 REQUIREMENTS	
7.3.5.	**Design and Development Verification**	7.3.6.	Design and Development Validation
7.3.6.	**Design and Development Validation**		Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use. Validation shall be completed prior to delivery or implementation of the product (see Note 1). As part of design and development validation, the organization shall perform clinical evaluations and/or evaluation of performance of the medical device, as required by national or regional regulations (see Note 2). **NOTE 1** *If a medical device can only be validated following assembly and installation at point of use, delivery is not considered to be complete until the product has been transferred to the customer.* **NOTE 2** *Provision of the medical device for purposes of clinical evaluations and/or evaluation of performance is not considered to be delivery* **Following successful completion of design verification, product shall be validated to ensure compliance with the product specification. Product validation shall be performed in accordance with an established and documented test plan using product that has been produced under production conditions including production tooling. A report of the results shall be prepared, and any differences between specification requirements and test data must be reconciled and documented prior to release.** **Records of the results of validation testing and any necessary actions shall be maintained.** ***EXEMPTION: Tyco Electronics conducts medical device performance evaluations in lieu of clinical evaluations.***
7.3.7.	**Control of Design and Development Changes**		
7.4.	**Purchasing**	7.4.1.	Purchasing Process
7.4.1.	**Purchasing Process**		The organization shall establish documented procedures to ensure that purchased product conforms to specified purchase requirements. **Purchasing, in consultation with the Business Unit, Product Engineering, Manufacturing, Supplier Quality Assurance and Legal, is responsible for supplier selection. The processes necessary to ensure that purchased product conforms with purchase requirements include TEC-1003, Supplier Performance Reporting and Continual Improvement Process; TEC-1005, Tyco Electronics Total Quality Managment Requirements for Suppliers; and TEC-1006, Approval of Suppliers.**
7.4.1.1.	**New Suppliers**		
7.4.1.2.	**Supplier Performance**		

TEC-1000		SUPPLEMENTARY ISO 13485: 2003 REQUIREMENTS	
			Risk management activities shall support the supplier selection process for materials used in medical applications.
7.4.2.	**Purchasing Information**	7.4.2.	Purchasing Information
			To the extent required for traceability given in 7.5.3.2, the organization shall maintain relevant purchasing information. i.e. documents (see 4.2.3) and records (see 4.2.4). **Purchase orders placed with suppliers shall define the product, the revision level and any additional quality assurance requirements beyond those established in Quality Specification TEC-1005, Tyco Electronics Total Quality Management Requirements for Suppliers.** **Risk management shall drive additional requirements as applicable including but not limited to:** • **Quality agreements;** • **Quality system requirements;** • **Traceability requirements; and** • **Data analysis.**
7.4.3.	**Verification of Purchased Products**	7.4.3.	Verification or Purchased Product
			Records of verification shall be maintained (see 4.2.4). **It shall be the responsibility of the Business Unit to determine the means of verifying that suppliers meet their contractual obligations related to the quality of the procured items. Evidence of conformity with the acceptance criteria shall be maintained and the records shall identify the individual(s) completing the inspection activities.**
7.5.	**Production and Service Processes**	7.5.1.	Control of Production and Service Provision
		7.5.1.1.	General Requirements
7.5.1.	**Control of Production and Service Processes**		The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable • The availability of documented procedures, documented requirements, work instructions, and reference materials and reference measurement procedures as necessary. • The implementation of defined operations for labeling and packaging.

TEC-1000	SUPPLEMENTARY ISO 13485: 2003 REQUIREMENTS	
		The organization shall establish and maintain a record (see 4.2.4) for each batch of medical devices that provides traceability to the extent specified in 7.5.3 and identifies the amount manufactured and amount approved for distribution. The batch record shall be verified and approved. **NOTE** *A batch can be a single medical device.* **Identification and planning of production and service processes that directly affect quality shall ensure that these processes are carried out under controlled conditions in accordance with documented procedures. The appopriate Business Unit functions shall:** • **Establish documented instructions, standard operating procedures and methods for manufacturing and inspection processes;** • **Ensure production equipment is qualified and maintained;** • **Ensure monitoring devices are qualified and maintained;** • **Ensure Process characteristics are adequately defined and qualified, validated and monitored;** • **Establish procedures for changes to a method, process or procedure including requirements for verification and revalidation;** • **Establish and implement labeling and packaging procedures where applicable.** **Records for each batch of medical devices that provides traceability to the extent specified in 7.5.3 and identifies the amount manufactured and amount approved for distribution shall be maintained. The batch record shall be verified and approved.**
	7.5.1.2.	Control of Production and Service Provision – Specific Requirements
	7.5.1.2.1.	Cleanliness of product and contamination control
		The organization shall establish documented requirements for cleanliness of product if • Product is cleaned by the organization prior to sterilization and/or its use, or • Product is supplied non-sterile to be subjected to a cleaning process prior to sterilization and/or its use, or • Product is supplied to be used non-sterile and its cleanliness is of significance in use, or • Process agents are to be removed from product during manufacture. If product is cleaned in accordance with the first two bullets above, the requirements contained in 6.4 a) and 6.4 b) do not apply prior to the cleaning process. **As applicable, documented procedures shall be established, maintained, and implemented defining product cleanliness and contamination controls.**

TEC-1000	SUPPLEMENTARY ISO 13485: 2003 REQUIREMENTS
	7.5.1.2.2. Installation Activities
	If appropriate, the organization shall establish documented requirements which contain acceptance criteria for installing and verifying the installation of the medical device. If the agreed customer requirements allow installation to be performed other than by the organization or its authorized agent, the organization shall provide documented requirements for installation and verification. Records of installation and verification performed by the organization or its authorized agent shall be maintained (see 4.2.4). ***EXCLUSION: Tyco Electronics does not perform installation for medical devices or device accessories.***
	7.5.1.2.3. Servicing Activities
	If servicing is a specified requirement, the organization shall establish documented procedures, work instructions and reference materials and reference measurement procedures, as necessary, for performing servicing activities and verifying that they meet the specified requirements. Records of servicing activities carried out by the organization shall be maintained (see 4.2.4). **NOTE** *Servicing can include, for example, repair and maintenance.* ***EXCLUSION: Tyco Electronics does not perform servicing for medical devices or device accessories.***
	7.5.1.3. Particular requirements for sterile medical devices
	The organization shall maintain records of the process parameters for the sterilization process which was used for each sterilization batch (see 4.2.4). Sterilization records shall be traceable to each production batch of medical devices (see 7.5.1.1). ***EXCLUSION: Tyco Electronics does not perform servicing for medical devices or device accessories.***

TEC-1000		SUPPLEMENTARY ISO 13485: 2003 REQUIREMENTS	
7.5.2.	**Validation of Production and Service Processes**	7.5.2.	Validation of Processes for Production and Service Provision
		7.5.2.1.	General Requirements
7.5.2.1.	**Process Monitoring and Operator Instructions**		The organization shall establish documented procedures for the validation of the application of computer software (and changes to such software and/or its application) for production and service provision that affect the ability of the product to conform to specified requirements. Such software applications shall be validated prior to initial use. Records of validation shall be maintained (see 4.2.4). **Production and service processes involving computer software applications shall be validated in accordance with documented procedures. This includes:** • **Software used as a component or accessory of a medical device; Software that is itself a medical device;** • **Software that is used in the production of a medical device; and** • **Software used in the implementation of the quality system.** **Production and service processes involving computer software applications including software used as a component shall be validated in accordance with documented procedures prior to use.** **Validation activities shall be conducted per defined, approved protocols. Records of validation shall be maintained.** **When changes or process deviations occur the responsible organization shall review and evaluate the process and perform revalidation where appropriate. These activities shall be documented. Records of revalidation shall be retained.**
7.5.2.2.	**Verification of Process Setups and Operational Changes**		
7.5.2.3.	**First Article Examination**		
		7.5.2.2.	Particular requirements for sterile medical devices
			The organization shall establish documented procedures for the validation of sterilization processes. Sterilization processes shall be validated prior to initial use. Records of validation of each sterilization process shall be maintained (see 4.2.4). ***EXCLUSION: Tyco Electronics does not provide sterile medical devices or device accessories.***
7.5.3.	**Product Identification and Traceability**	7.5.3.	Identification and Traceability
		7.5.3.1.	Identification
7.5.3.1.	**Inspection and Test Status**		The organization shall identify the product by suitable means throughout product realization, and shall establish documented procedures for such product identification. The organization shall establish documented procedures to ensure that medical devices returned to the organization are identified and distinguished from conforming product (see 6.4 d).

TEC-1000	SUPPLEMENTARY ISO 13485: 2003 REQUIREMENTS	
		Documented procedures shall define the manner for identifying all production materials in process and in inventory ensuring that product is identifiable as to part number, and traceable to revision level, and inspection status. Documented procedures shall also define the manner of identifying and/or segragating returned medical devices or device accessories from conforming product.
	7.5.3.2.	Traceability
	7.5.3.2.1.	General
		The organization shall establish documented procedures for traceability. Such procedures shall define the extent of product traceability and the records required (see 4.2.4, 8.3 and 8.5). Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4). **NOTE** *Configuration management is a means by which identification and traceability can be maintained.* **All production materials in process and in inventory shall be identifiable as to part number, and shall be traceable to revision level, and inspection status. A comparable identification methodology shall apply to sample / prototype / preproduction parts which must meet customer requirements. Configuration control shall be maintained in accordance with documented procedures for product and process change control.**
	7.5.3.2.2.	Particular requirements for active implantable medical devices and implantable medical devices
		In defining the records required for traceability, the organization shall include records of all components, materials and work environment conditions, if these could cause the medical device not to satisfy its specified requirements. The organization shall require that its agents or distributors maintain records of the distribution of medical devices to allow traceability and that such records are available for inspection. Records of the name and address of the shipping package consignee shall be maintained (see 4.2.4). ***EXCLUSION: Tyco Electronics does not manufacture active implantable medical devices or device accessories.***

TEC-1000		SUPPLEMENTARY ISO 13485: 2003 REQUIREMENTS	
		7.5.3.3	Status Identification
			The identification of product status shall be maintained throughout production, storage, installation and servicing of the product to ensure that only product that has passed the required inspections and tests (or released under an authorized concession) is dispatched, used or installed. **All production materials in–process or in inventory shall be identifiable as acceptable for further processing or shipment. This marking shall appear on each unit container used for handling and storage. This marking may be on cartons, reel tags, routing cards, product travelers, or any ther suitable location, provided there is a clear indication that prior verification operations have been performed. The verification status indication shall permit identification of the operator(s) / inspector(s) who performed the prior inspection(s) or review. Records shall be maintained of authorized identifiers.** **When the status is identifiable through machine–readable code, there shall be sufficient information provided to identify verification status when the reader is not available. (TEC-1000)**
7.5.4.	**Control of Customer Property**	7.5.4.	Customer Property
			NOTE *Customer property can include intellectual property or confidential health information.* **As applicable Business Units shall have procedures that define the identification and control of customer owned property including intellectual property.**
7.5.5. **7.5.5.1**	**Product Preservation** **Shelf-Life**	7.5.5.	Preservation of Property
			The organization shall establish documented procedures or documented work instructions for preserving the conformity of product during internal processing and delivery to the intended destination. **Documented procedures shall be established and maintained for handling, storage, packaging, preservation and delivery of product. Methods for handling product that prevents damage or deterioration shall be provided.** **Designated distribution warehouse storage areas, general warehouse storage areas or stock rooms are utilized to prevent damage or deterioration of product, pending use or delivery. Appropriate methods for authorizing receipt to and dispatch from such areas shall be stipulated. Each stocking location shall apply appropriate methods for preservation and segregation of product to ensure that material or product will remain undamaged pending use or delivery. In order to detect deterioration, each stocking area shall, at appropriate intervals, assess the condition of the product.**

TEC-1000		SUPPLEMENTARY ISO 13485: 2003 REQUIREMENTS	
			Inventory systems to optimize inventory turns over time, assure stock rotation, and minimize inventory levels shall be utilized. **Packaging and labeling / marking processes shall be controlled to the extent necessary to ensure conformance to established requirements. This shall include systems to conform to specific customer packaging and labeling requirements. (TEC-1000)** The organization shall establish documented procedures or documented work instructions for the control of product with a limited shelf-life or requiring special storage conditions. Such special storage conditions shall be controlled and recorded (see 4.2.4). **As established in a documented procedure, materials that have a shelf life shall be clearly marked with an expiration date, or a date of manufacture that can be used to calculate an expiration date. Materials shall not be used past the expiration date. When materials require special storage conditions, those conditions shall be documented and controlled.**
7.6.	**Control of Inspection, Measuring, and Testing Equipment**	7.6.	Control of Monitoring and Measuring Devices
			The organization shall establish documented procedures to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements. **NOTE** *See ISO 10012 for guidance related to measurement management systems.* **Documented procedures shall be established and maintained defining a calibration program that controls the accuracy of measuring and test equipment used for determining conformance of parts and materials to technical requirements. This procedure shall conform to the requirements and intent of ISO 10012.** **A Metrology function shall be responsible for the establishment, operation and maintenance of the measurement management system.** **Risk management procedures shall define risk assessment requirements for equipment found to be out of specification.**

8. MEASUREMENT, ANALYSIS AND IMPROVEMENT

TEC-1000		SUPPLEMENTARY ISO 13485: 2003 REQUIREMENTS	
8.1.	**Measurement, Analysis, and Improvement – General**	8.1.	General
			The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed • To maintain the effectiveness of the quality management system. **NOTE** *National or regional regulations might require documented procedures for implementation and control of the application of statistical techniques.* **Monitoring, measurement, analysis, and improvement processes shall be implemented to demonstrate product conformity, ensure quality management system conformity, and maintain the effectiveness of the quality management system.**
8.1.1.	**Statistical Techniques**		
8.2.	**Monitoring and Measurement**	8.2.1.	Feedback
8.2.1.	**Customer Satisfaction**		As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to whether the organization has met customer requirements. The organization shall establish a documented procedure for a feedback system (see 7.2.3.c) to provide early warning of quality problems and for input into the corrective and preventive action processes (see 8.5.2 and 8.5.3). If national or regional regulations require the organization to gain experience from the post-production phase, the review of this experience shall form a part of the feedback system (see 8.5.1). **Information related to customer perception as to whether Tyco Electronics has met customer requirements shall be included as a QMS performance measure. (TEC-1000)** **The manner for determining customer satisfaction shall be defined in a documented procedure and include a method for collecting customer satisfaction data, including the frequency of determination, and how objectivity and validity are assured. Trends in customer satisfaction and key indicators of customer dissatisfaction shall be documented and supported by objective information. As appropriate, these trends should be compared to those of competitors, or benchmarks, and reviewed by top management.** **Customer satisfaction / dissatisfaction will be included as a topic within the top level management review. If applicable, actions taken will be monitored within the management review process.**

TEC-1000		SUPPLEMENTARY ISO 13485: 2003 REQUIREMENTS	
8.2.2.	**Internal Assessments and Audits**	8.2.2.	Internal Audit
		NOTE	*See ISO 19011 for guidance related quality auditing.*
8.2.2.1.	**Manufacturing Process Audits**		**Each organization shall conduct assessments of the quality management system in accordance with documented procedures at regular intervals based on the status and importance of the activity. These assessments are conducted to verify compliance with planned arrangements and to determine the adequacy, effectiveness, and suitability of the quality management system to meet the objectives of the Tyco Electronics Quality Management System and the requirements of ISO 13485: 2003, Medical devices - Quality management systems – Requirements for regulatory processes.**
8.2.2.2.	**External Assessments**		**Assessments of the quality management system shall be carried out by qualified personnel independent of those having direct responsibility for the area being assessed and should cover all shifts. Follow–up assessment activities shall verify and record the implementation and effectiveness of the corrective action taken.**
8.2.3.	**Process Monitoring and Measurement**		**Results of these assessments shall be reviewed by management as feedback for continual improvement and verification of conformance to quality management system requirements. Records of such assessments and reviews shall be maintained.**
8.2.4.	**Monitoring and Measurement of Product**	8.2.4.	Monitoring and Measurement of Product
		8.2.4.1.	General Requirements
8.2.4.1.	**In-Process Inspection**		The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1) and documented procedures (see 7.5.1.1).
8.2.4.2.	**Final Inspection**		Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed.
			Product characteristics shall be measured and monitored throughout the manufacturing process to ensure that the product meets the established requirements. These inspection and testing activities shall be performed in accordance with documented procedures. Evidence of conformity with the acceptance criteria shall be maintained and the records shall identify the individual(s) completing the inspection activities. Product shall not be released until all inspection activities have been satisfactorily completed.

TEC-1000		SUPPLEMENTARY ISO 13485: 2003 REQUIREMENTS	
		8.2.4.2.	Particular Requirements for Active Implantable Devices and Implantable Devices
			The organization shall record (see 4.2.4) the identity of personnel performing any inspection or testing. ***EXCLUSION: Tyco Electronics does not manufacture active implantable medical devices or device accessories.***
8.3.	**Control of Nonconforming Product and Materials**	8.3.	Control of Nonconforming Product
			The organization shall deal with nonconforming product by one or more of the following ways: • By authorizing its use, release or acceptance under concession. The organization shall ensure that nonconforming product is accepted by concession only if regulatory requirements are met. Records of the identity of the person(s) authorizing the concession shall be maintained (see 4.2.4). **Nonconforming product may be released for use by concession when regulatory and customer requirements are met and a deviation has been processed and approved. All deviations shall clearly specify the temporary limits of acceptability, state the definitive corrective action and be approved by the appropriate engineering functions and applicable customers. If the affected dimension, feature, or characteristic is a specified customer requirement, no deviation shall be issued unless the customer has been granted a documented concession. This applies equally to product or services purchased from suppliers. The Business Unit shall concur with any requests by a supplier before submission to the customer. The Business Unit shall maintain records of the expiration date or quantity authorized. The Business Unit shall also ensure compliance with the original or superseding specification and requirements when the deviation expires. Internally, products shipped under deviation shall reference the deviation number on each unit container. Material shipped with authorization for concession shall be identified on each shipping container as required by the customer. Maintained records of deviations shall include the names of individuals authorizing the concession.** If product needs to be reworked (one or more times), the organization shall document the rework process in a work instruction that has undergone the same authorization and approval procedure as the original work instruction. Prior to authorization and approval of the work instruction, a determination of any adverse effect of the rework upon product shall be made and documented (see 4.2.3 and 7.5.1).

TEC-1000		SUPPLEMENTARY ISO 13485: 2003 REQUIREMENTS	
			Nonconforming material shall be evaluated and dispostioned as appropriate. When applicable rework / repair instructions shall be provided and the material shall be re-inspected to an approved quality plan prior to further processing or shipment. The rework instructions shall take into consideration and document any possible adverse effect on the product and must be approved by the same functional organizations responsible for approving initial manufacturing instructions as well as Quality Assurance. **Risk management shall support the nonconforming disposition process and the review and approval of rework instructions.**
8.4.	**Measurement and Analysis of Organizational Performance**	8.4.	Analysis of Data
			The organization shall establish documented procedures to determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate if improvement of the effectiveness of the quality management system can be made. The analysis of data shall provide information relating to • Feedback (see 8.2.1). Records of the results of the analysis of data shall be maintained (see 4.2.4). **The Quality Assurance Director / Manager and each Business Unit President / Vice-President shall have the responsibility to maintain performance data, Tyco Electronics directed quality measures, customer satisfaction and / or dissatisfaction, and operational performance (e.g. productivity, efficiency, effectiveness) for key products and services. Customer feedback is evaluated through several tools that may include: customer complaints, customer feedback responses, the Quality Operating System (QOS) process, reports and information from Field Sales and Product Management and from Industry Reports. Records of data analysis shall be maintained.**
8.5. **8.5.1.**	**Improvement** **Continual Improvement**	8.5.1.	General
			The organization shall identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review. **The Business Unit shall ensure the continued suitability and effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, risk management, and management review.** The organization shall establish documented procedures for the issue and implementation of advisory notices. These procedures shall be capable of being implemented at any time.

TEC-1000	SUPPLEMENTARY ISO 13485: 2003 REQUIREMENTS
	Advisory notices to customers shall be implemented as applicable. A documented procedure shall establish the advisory notice methodology specific to medical products. Records of all customer complaint investigations shall be maintained (see 4.2.4). If investigation determines that the activities outside the organization contributed to the customer complaint, relevant information shall be exchanged between the organizations involved (see 4.1). If any customer complaint is not followed by corrective and/or preventive action, the reason shall be authorized (see 5.5.1) and recorded (4.2.4). **For the purposes of medical devices the term "complaint" means: Any written, electronic, or oral communication that alleges deficiency related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device or a device accessory after it is released for distribution.** **As a contract manufacturer Tyco Electronics does not distribute medical devices or device accessories. In support of regulatory requirements Tyco Electronics will consider the complaint definition applicable to medical products produced by Tyco Electronics and will investigate all reports alleged of non-conformance accordingly. Records of investigations shall be maintained.** **Where a nonconformance is identified, the responsible Business Unit shall determine root cause; implement corrective and preventive actions according to documented procedures. If the root cause is determined to be related to a supplier, both internally and externally, the Business Unit shall drive additional corrective action when applicable. Unless there is a specific format required by the customer, the TECHS format shall be utilized for all complaints received from external customers. If any customer complaint is not followed by corrective and/or preventive action, the reason shall be recorded and approved.** If national or regional regulations require notification of adverse events that meet specified reporting criteria, the organization shall establish documented procedures for such notification to regulatory authorities. **As a contract manufacturer Tyco Electronics is not responsible for Advisory Notices to regulatory agencies specific to medical devices or device accessories.**

TEC-1000	SUPPLEMENTARY ISO 13485: 2003 REQUIREMENTS
8.5.2. Corrective Action	8.5.2. Corrective Action
	A documented procedure shall be established to define the requirements for • Determining and implementing action needed, including, if appropriate, updating documentation (see 4.2). • Recording of the results of any investigation and action taken (see 4.2.4). • Reviewing the corrective action taken and its effectiveness. **In all cases where a nonconformance is identified or where analysis indicates a nonconformance, the responsible function shall be notified in writing and shall receive a corrective action statement. The corrective action plan shall be reviewed with the function(s) responsible for implementation of the corrective action. The function responsible for corrective action shall use disciplined problem solving methods and mistake proofing methodologies.** **The Tyco Electronics Complaint Handling System (TECHS) shall be used to manage all customer complaints. This on-line software program will assign corrective action to the owning Business Unit such that the issues may be resolved in a timely fashion as defined by the customer.** **Where a nonconformance is identified, the responsible Business Unit shall implement corrective action according to documented procedures. Unless there is a specific format required by the customer, the TECHS format shall be utilized for all complaints received from external customers. If any customer complaint is not followed by corrective and/or preventive action, the reason shall be recorded and approved.** **Consideration should be given to utilizing the Eight Discipline process when responding to internal failures. Corrective action shall be to the degree appropriate to the magnitude of the problem and commensurate to the risks encountered. Understanding the benefits, risks, and costs are crucial in maintaining a balance in implementing the Quality Management System Management.**

TEC-1000	SUPPLEMENTARY ISO 13485: 2003 REQUIREMENTS
8.5.3. Preventive Action	8.5.3. Preventive Action
	A documented procedure shall be established to define the requirements for • Recording the results of any investigations and action taken (see 4.2.4). • Reviewing preventive action taken and its effectiveness. **Steps shall be taken according to documented procedures to eliminate potential nonconformances related to product and quality system and regulatory compliance. These steps shall include recording investigation results and confirming action effectiveness. The degree of preventive action taken should be dependent on and related to the risk, size and nature of the potential problem and its effect on product and compliance.** **Records of preventive action shall be maintained and shall be included as an input for management review.**

05/21/2009 15:05 IFAX htscan@Lr.org → Ashley Davis 001/002

LRQA

www.lrqausa.com
T (281) 398-7370
F (281) 398-7337
E management-usa@lrqa.com

LRQA, Inc.
Lloyd's Register Quality Assurance, Inc
1401 Enclave Pkwy., Suite 200
Houston, TX 77077
USA

Bill Arbogast
Tyco Electronics Corporation
2100 Paxton Street, MS 18-11
Harrisburg, PA 17105

May 21, 2009

Dear Mr. Arbogast:

A special assessment document review was undertaken by LRQA to examine Tyco Electronics Corporation's Global Quality Management System Process (quality manual) TEC-1018. After verifying correction of non-conformances and associated revision of the document, LRQA has determined that TEC-1018 conforms to the quality manual requirements of ISO 13485:2003.

This statement of conformance is limited, applying only to Tyco Electronics Corporation's top level quality management document and as such does not meet the requirements for a full Stage 1 assessment as described in ISO/IEC 17021 or LRQA assessment procedures.

Sincerely,

Krissi Temple
QMS Technical Manager