STANDARD OPERATING PROCEDURE

Title: Document Control and Change Procedure

Effective Date:_____

Approvals: (sign and date)

_____	_____	_____
Responsible Department Head	Technical Authority	QA/QC

1. PURPOSE

1.1 To describe the procedure for creation, review and approval of all product and manufacturing related documents (including, but not limited to all documents that pertain to the purchase, manufacture, testing, storage and handling of product).

1.2 To describe the procedure for filing, distribution and archiving of manufacturing related documents and other documents to which change control applies.

1.3 To describe the procedure for document change control.

2. SCOPE

2.1 This procedure applies to all manufacturing related documents which comprise the Device Master Record (DMR) including:

- Product Number Specifications (PNS)
- Manufacturing Batch Records (MBR)
- Standard Operating Procedures (SOP)
- Product Drawings (DWG)
- Qualification and Validation Documents (QVD)

2.2 Documents which impact European operations are covered by this procedure. The special handling (review and approval) procedures are detailed in section 10.0.

2.3 The general principles of document change control as outlined in this SOP are also applicable to Drawings (DWG). However, the generation, change control, archiving procedures specific for Drawings are explained in Section 11.0, because of the numerous exceptions involved.

2.4 This procedure applies to all non-manufacturing related Standard Operating Procedures which may be required to comply with regulatory requirements which impact the company's operations (as stated in the Quality Manual).

2.5 At the discretion of the generating department, this procedure may apply to any other company procedures which may be deemed appropriate to control under the system described in this procedure. However, the Director of QA/QC will ultimately determine the appropriateness of other company procedures which may be outside of the intended scope of this procedure.

2.6 Significant document changes (defined as changes to manufacturing or testing process or to product form, fit or function) must be reviewed and approved before the change can be instituted. Discrepancey reports must be used for exceptions.

3. RESPONSIBILITY

3.1 Originator is responsible for:

3.1.1 Writing documents or document revisions.

3.1.2 Obtaining a DCO number prior to DCR routing to assure that the document is not being revised by another employee.

3.1.3 Determining what other documents might be impacted by the proposed change and initiating changes to affected related documents.

3.1.4 Obtaining and resolving the comments of the draft document reviewers.

3.1.5 Alerting all affected departments of changes planned to controlled documents.

3.2 Document Control is responsible for:

3.2.1 Assigning DCO numbers and checking the DCO log to assure that documents entering the DCR/DCO process are not already in the change control system.

3.2.2 Controlling the final review and approval routing of documents (DCO review).

3.2.3 Maintaining the Master Document Files (MDF).

3.2.4 Maintaining the Authorized Document Manuals (ADM).

3.3 Reviewers are responsible for:

3.3.1 Assuring the accuracy, technical content and completeness of the document.

3.3.2 Returning any DCR that does not have a DCO number assigned to the originator.

3.4 Quality Assurance is responsible for assuring that:

3.4.1 This procedure is followed.

3.4.2 The document has been assigned the correct number catagory.

3.4.3 The title is short and accurate.

3.4.4 All documents covered by this procedure meet documentation requirements.

3.4.5 All product specifications and manufacturing requirements are appropriate to ensure product quality.

3.4.6 New documents do not conflict with existing procedures or protocols.

3.4.7 Documents do not compromise regulatory requirements.

3.5 Technical Authority is responsible for assuring that:

3.5.1 Procedures and instructions in documents follow sound scientific/technical principles, and that calculations are correct from a theoretical and practical standpoint.

3.5.2 A validation impact assessment has been performed by appropriate personnel if applicable to the new or revised document.

4. REFERENCES AND APPLICABLE DOCUMENTS

4.1 Company Quality Manual for references to applicable regulatory requirements.

4.2 09-0001-FRM-1.0, Document Change Request Form

4.3 09-0007-SOP-1.0, Device Master Record

4.4 12-0011-SOP-1.0, SOP Document Preparation

4.5 12-0015-SOP-1.0, QVD Document Preparation
4.6 12-0016-SOP-1.0, PNS Document Preparation
4.7 12-0020-SOP-1.0, MBR Document Preparation
4.8 12-0049-SOP-1.0, Engineering Documentation, Change and Control
4.9 09-0180-SOP-1.0, EC Notification of Change Procedure
4.10 09-0083-SOP-1.0, FDA Notification of Change
4.11 09-0004-SOP-1.0, Discrepancy Report Procedure
4.12 10-0025-SOP-1.0, Part Numbering

5. MATERIALS AND EQUIPMENT

5.1 Master Document Index

5.2 Authorized Document Manuals (ADMs)

5.3 Master Document Files (MDFs)

5.4 Document Change Order (DCO) Log

5.5 Master Document Style Sheets and Master Document Format Templates. The style sheet and template for each document type are contained in individual SOPs for each document type (see section 4.0).

5.5.1 Master Document Style Sheets, which describe the font, margin, type style and type size requirements, have been developed for each of the following document types:

- Product Number Specifications (PNS) - 12-0016-SOP-1.0
- Manufacturing Batch Records (MBR) - 12-0020-SOP-1.0
- Standard Operating Procedures (SOP) - 12-0011-SOP-1.0
- Qualification and Validation Documents (QVD) - 12-0015-SOP-1.0
- Drawings (DWG) - 12-0049-SOP-1.0

5.5.2 Master Document Format Templates, which describe the document content requirements and illustrate the format, have been prepared for each of the document types listed in Section 5.5.1.

5.6 For the convenience of document originators, Master Document Format Templates are available in the MS Word template directory. New MS Word documents may be created from these templates by selecting the **File**, **New...** menu commands and then selecting either "QVD-PROT", "QVD-RPRT", "NEWSOP", "NEWPNS", "NEWMBR", "BUFMBR" from the "New" dialog box.

6. HEALTH AND SAFETY CONSIDERATIONS

6.1 None

7. DOCUMENTATION REQUIREMENTS

7.1 Document Change Request (DCR) form - Attachment E *(two pages)*
7.2 Materials Control Review (MCR) form - Attachment G
7.3 Regulator Assessment Review (RAR) form - Attachment J
7.4 Document Change Order (DCO) form - Attachment H
7.5 Document Archiving and Distribution (DAD) form - Attachment I
7.6 Annual Document Review form - Attachment K
7.7 Master Document Index (with Document Distribution Matrixes)

8. DOCUMENT CREATION, REVIEW AND APPROVAL PROCEDURE

Note: An overview flowchart of the document creation, review, approval, distribution and archive procedure is included in this SOP as Attachment A.

8.1 Document Creation

8.1.1 Documents will be written or prepared by an individual who is knowledgeable about the part or process being documented. In the case of SOPs, for example, this might be the person who performs the work or who has direct responsibility for the performance of the work. The person who writes or prepares the document is called the Originator.

8.1.2 The draft document is prepared using the approved standard format. Document templates with the approved standard format are included in individual SOPs for each document type. Contact Document Control for a copy of the appropriate SOP. Templates are also available on the company's computer network.

8.1.3 For documents other than Drawings, the new document can be identified on the network (or on transfer disk) using the following convention:

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where the first six characters are used for the document number, the seventh and eighth characters indicate the dash number (01, 02, or 51 etc.) and the final three characters (after the period) indicate the document type (MBR, PNS, SOP, etc.)

8.1.4 Documents should be written clearly, creating a document that is specific and informative, yet flexible and practical.

8.1.5 If applicable, data to support the document must be compiled and attached to the draft document. For example, data to support test specification acceptance criteria, production time limits, selection of authorized manufacturers, etc. should be included in the Document Change Request (DCR) packet.

8.1.6 Determine a clear, concise title for the document. Keep in mind that the title will need to contain all key words that may be useful in a computer search for the document at some future date. Document titles also need to be consistent with existing related documents.

8.1.6.1 Document Control can be contacted for assistance with naming QVDs and SOPs.

8.1.6.2 Materials Control can be contacted for assistance with naming PNSs, MBRs and DWGs.

8.1.7 In the case of new product development, the designer of the new product will work closely with the Originator to assure accurate transfer of product design information into the document.

8.1.8 Document identification numbers for new documents (or document revision letters for existing documents) are assigned by Document Control using the Document Identification Number Scheme (Attachment B).

Note: Part numbers are assigned by Engineering. Document Control incorporates the part number assigned by Engineering into the document identification number.

8.1.8.1 When a new document number is requested, Document Control records the document number, the originator/requester, the document title and the date on the appropriate index.

8.1.8.2 The Document Indexes are maintained by Document Control.

8.1.8.3 Assigned numbers will not be reissued to another document without approval from the Director of QA/QC.

8.2 Initiation of Document Change Request

Note: If the only change to a document is that required by a DR, then the signed DR may take the place of a DCR. Therefore the document can go straight to DCO routing.

8.2.1 The Originator fills out the top portion of the Document Change Request (DCR) form including the document title, document number (including type and current revision), a description of the change, a brief statement regarding the reason for the change, and a list of documents affected by the change (if applicable). The description of the change should be quite specific so that the information can be utilized for QA annual summaries and reports. The document(s) to be changed or the draft document(s) are attached to the DCR.

8.2.1.1 For SOPs and QVDs, approval of changes to the document results in a change in the revision letter of the document.

8.2.1.2 For MBRs, PNSs, and DWGs, approval of changes in form, fit or function result in a change in the part number and a change in the revision letter of the document.

8.2.1.3 For MBRs, PNSs and DWGs, approval of changes which do not affect form, fit or function results in a change in the revision letter of the document.

8.2.1.4 To improve routing efficiency, each document should have its own individual DCR form. The exception to this would be in the case where a change impacts multiple documents. For example, a change to a single part may impact the MBR, PNS and DWG for that part number. An addendum to the DCR form has been provided for in cases where more than six documents are being routed on the same DCR (see Attachment F).

8.2.1.5 Do not group multiple documents on a single DCR that require a different set of DCR reviewers.

8.2.1.6 The Originator is responsible for initiating changes to affected related documents. For assistance in determining affected related documents, the Originator should contact their supervisor, Materials Control, and/or Document Control.

8.2.1.7 Additional documents may be added to the DCR packet to assist reviewers with the review process. These documents are marked “For Reference Use Only”.

8.3 Materials Control Review

If the document affects a part or product (PNS, MBR or DWG), a Materials Control Review (MCR) form **must** be completed (Attachment G). Note: In some cases, changes to SOPs or QVDs may also require a Materials Control Review when the changes affect a part or product.

8.3.1 The Originator provides information required by Materials Control.

8.3.1.1 A description of the change to the identified part number.

8.3.1.2 What other part numbers are affected by the change.

8.3.1.3 If the estimated cost of the new part or revised part is known, order lead time and/or availability and storage location, this information should also be indicated on the MCR.

8.3.1.4 The Originator recommends whether the change needs to be implemented immediately, thereby obsoleting all existing parts in inventory. Alternately, the change may be implemented after all existing inventory has been exhausted, all inventory has been reworked, or inventory is not affected.