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| **1. DCO NUMBER:** | |  | | | | | **10. EFFECTIVE DATE & FINAL RELEASE** | | | | | | | | | | |
| Changes By: | |  | | | | | Effective Date: | | | |  | | | | | | |
| Date: | |  | | | | | Released By: | | | |  | | | | | | |
| **2. TYPE OF REQUEST(S)** | | | | New Document | | | | Change | | | | | | Obsolete | | | |
| **3. TYPE(S) OF CHANGE(S)** | | | | Quality System Document | | | | | | | | Labeling Document | | | | | |
|  | | | | Design & Development Document | | | | | | | | Supplier Document | | | | | |
| Marketing Materials | | | | Manufacturing Document (SOP,WI,etc.) | | | | | | | | Other: | | | | | |
| **4. DOCUMENTS** | | | | | | | | | | **5. PRODUCT DISPOSITION** | | | | | | | |
| Title | | | | | Number | | From  Rev: | | To  Rev: | Next  PO | | WIP | Finished Goods | | 1. Incorporate change 2. Do not incorporate change 3. Use as is 4. Scrap 5. Not applicable | | |
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| **6. DISPOSITION DETAILS** (plan and/or justification; required if Section 5 is applicable ) | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | |
| **7. DESCRIPTION OF CHANGE(S) AND JUSTIFICATION** (what is changing, why it changed, and why it is acceptable to change) | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | |
| **8. IMPACT ASSESSMENT** (impact to validations, quality systems, medical device, regulatory compliance, etc.) | | | | | | | | | | | | | | | | | |
| **Training Required** (if no, explain) | | | Yes | | No | **Re-Validation Required** (if no, explain) | | | | | | | Yes | | | | No |
| **Supplier Notification Required** | | | Yes | | No | **Impact on QMS** (if yes, explain) | | | | | | | Yes | | | | No |
| **Impact on Medical Device** (if yes, explain) | | | Yes | | No | **Regulatory Impacts** (if yes, explain) | | | | | | | Yes | | | | No |
|  | | | | | | | | | | | | | | | | | |
| **9. APPROVALS** | | | | | | | | | | | | | | | | | |
| **Department** | **Required?** | | | | **Signature** | | | | | | | | | | | **Date** | |
| Quality and Regulatory | Yes | | | No |  | | | | | | | | | | |  | |
| Engineering | Yes | | | No |  | | | | | | | | | | |  | |
| Operations | Yes | | | No |  | | | | | | | | | | |  | |
| Sales and Marketing | Yes | | | No |  | | | | | | | | | | |  | |
| Other: | Yes | | | No |  | | | | | | | | | | |  | |