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				Proprietary & Confidential Information
FINISHED PRODUCT RELEASE				

7.0 PROCEDURE

7.1 Manufacture Finished Products

- 7.1.1 Manufacturing personnel complete all activities required in the DMR for finished products and record required information in the DHR(s). DHRs include at a minimum:
- Date(s) of manufacture
 - Quantity manufactured
 - Quantity to be released for distribution
 - The acceptance records that demonstrate the device was manufactured according to the DMR
 - The primary identification label and labeling used for each production unit
 - Any device identification and control numbers used
- 7.1.2 Acceptance records demonstrate that product meets acceptance criteria and include at a minimum:
- Acceptance activities performed
 - Dates acceptance activities were performed
 - The results
 - The signature of the individual conducting the acceptance activity
 - The equipment used (where appropriate)
- 7.1.3 Manufacturing personnel perform a review of the completed DHR(s) for accuracy and compliance with all Company and device specific procedures and standards. This review ensures that all activities required by the DMR are complete. If issues, discrepancies, or nonconformances are identified, handle them according to the applicable Company procedure(s) before proceeding.
- 7.1.4 Manufacturing personnel complete applicable sections of the Finished Product Release Record, MD47 - RF1, to identify the unit, lot, or batch to be released and to document summary information used for product release.
- 7.1.5 The Manufacturing Supervisor or Manager signs the Finished Product Release Record and provides it to Quality Control along with the DHR(s).

7.2 Perform Final Inspection & Test

- 7.2.1 Quality Control performs final inspection and test procedures as required by the DMR and documents the results in the DHR(s).

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