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Policy: A Device Master Record will be prepared and maintained for all devices (products) manufactured or under development.

Purpose: To prescribe the responsibilities for preparing Device Master Records (DMR) and to ensure the completeness of DMR indexes (indices).

Scope: All equipment specifically including medical devices manufactured by the Company are covered under this procedure.

Definitions: Device Master Record (DMR) - A compilation of records containing the description, design, formulation, specifications, complete manufacturing procedures, quality assurance requirements, and labeling of a finished device. In addition to the device specifications, a DMR contains documents that cover typical manufacturing activities including procurement, assembly, labeling, testing, and inspection and packaging.

DMR Index - Table of contents for the master record of a device; can contain information on the breakdown of the device into assemblies and/or manufacturing steps. Called a "document plan" during planning and early development of a new product.

Procedure:

1.0 PREPARATION OF DEVICE MASTER RECORD

1.1 Upon completion of the design phase of a device, a formal document plan will be initiated and will be called the Device Master Record. The configuration and structure of the master record is determined by the Engineering and Manufacturing managers.

After agreement, the master record will be created, document numbers assigned, status of drawings indicated and the record approved by Engineering and Manufacturing. See ENG104-1 DEVICE MASTER RECORD CONTENTS for a listing of items that may appear in a Device Master Record.

1.2 Upon compilation of all documents to be included in the Master Record, a ENG104-2 DEVICE MASTER RECORD INDEX shall be prepared to identify all items in the record and location(s) of these records.

1.3 Complete specifications of the device will be prepared and included as part of the Master Record (see ENG104-3 DEVICE SPECIFICATION EXAMPLE). The device or product specification is a specific document that briefly describes and

Engineering Procedures Manual

Michael Brown



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