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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

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Table of Contents Engineering Procedure Template

1. Understanding the eBook Engineering Procedure Template
 - The Rise of Digital Reading Engineering Procedure Template
 - Advantages of eBooks Over Traditional Books
2. Identifying Engineering Procedure Template
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in an Engineering Procedure Template
 - User-Friendly Interface
4. Exploring eBook Recommendations from Engineering Procedure Template
 - Personalized Recommendations
 - Engineering Procedure Template User Reviews and Ratings

- Engineering Procedure Template and Bestseller Lists
- 5. Accessing Engineering Procedure Template Free and Paid eBooks
 - Engineering Procedure Template Public Domain eBooks
 - Engineering Procedure Template eBook Subscription Services
 - Engineering Procedure Template Budget-Friendly Options
- 6. Navigating Engineering Procedure Template eBook Formats
 - ePub, PDF, MOBI, and More
 - Engineering Procedure Template Compatibility with Devices
 - Engineering Procedure Template Enhanced eBook Features
- 7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of Engineering Procedure Template
 - Highlighting and Note-Taking Engineering Procedure Template
 - Interactive Elements Engineering Procedure Template
- 8. Staying Engaged with Engineering Procedure Template
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers Engineering Procedure Template
- 9. Balancing eBooks and Physical Books Engineering Procedure Template
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection Engineering Procedure Template
- 10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
- 11. Cultivating a Reading Routine Engineering Procedure Template
 - Setting Reading Goals Engineering Procedure Template
 - Carving Out Dedicated Reading Time
- 12. Sourcing Reliable Information of Engineering Procedure Template
 - Fact-Checking eBook Content of Engineering Procedure Template
 - Distinguishing Credible Sources

13. Promoting Lifelong Learning
 - Utilizing eBooks for Skill Development
 - Exploring Educational eBooks
14. Embracing eBook Trends
 - Integration of Multimedia Elements
 - Interactive and Gamified eBooks

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