



Document ID ENG104	Title DEVICE MASTER RECORD	Print Date mm/dd/yyyy
Revision 0.0	Prepared By Preparer's Name / Title	Date Prepared mm/dd/yyyy
Effective Date mm/dd/yyyy	Reviewed By Reviewer's Name / Title	Date Reviewed mm/dd/yyyy
	Approved By Final Approver's Name / Title	Date Approved mm/dd/yyyy

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

Phillip A. Cloud



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Developing and Managing Engineering

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Table of Contents Engineering Procedures Manual

1. Understanding the eBook Engineering Procedures Manual
 - The Rise of Digital Reading Engineering Procedures Manual
 - Advantages of eBooks Over Traditional Books
2. Identifying Engineering Procedures Manual
 - 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 Procedures Manual
 - User-Friendly Interface
4. Exploring eBook Recommendations from Engineering Procedures Manual

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

- Fact-Checking eBook Content of Engineering Procedures Manual
- 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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