1 Purpose

The purpose of this procedure is to define the method for documenting and maintaining a Device Master Record (DMR), also known as a Medical Device File, at MBio Diagnostics, Inc.

2 Scope

This procedure applies to all medical devices manufactured by MBio Diagnostics.

This procedure complies with MBio's Quality Management System and with all relevant standards and applicable regulations as listed in the Quality Manual (QM001). Additional regulatory standards or guidance documents may be referenced within this procedure.

3 Additional Regulatory Standards or Guidance Documents Referenced

N/A

4 Procedure

4.1 The DMR is assembled as a reference index capturing all relevant documents released per SOP-5000-001 Document and Records Control. The format of this reference index is analogous to how a Bill of Materials organizes parts to point to Drawings. It will be released as a Spreadsheet (SS) per SOP-5000-001 Document and Records Control.

4.2 The DMR is specific to each device family and references or contains the following types of documents (with document prefix noted in parentheses). Please note that not all types of documents specified in this section are applicable to all devices:

4.2.1 General description of the medical device, intended use/purpose, labeling and any instruction for use:

4.2.1.1 Labeling – product labels, instructions for use, marketing literature (L)

4.2.2 Specifications for Product

4.2.2.1 Bill of Materials (BOM)

4.2.2.2 Drawings (DWG)

4.2.2.3 Part Specifications (PS)

4.2.2.4 Finished Product Specifications (FPS)

4.2.3 Specifications and procedures for manufacturing, packaging, storage, handling and distribution

4.2.3.1 Work Instructions (WI)

4.2.3.2 Travelers (TRA)

4.2.3.3 Batch Records (BR)

4.2.3.4 Forms (FM)

4.2.3.5 Work Orders (WO)

4.2.3.6 Manufacturing Plan (MP)

4.2.3.7 Diagrams (DIA)

4.2.3.8 Part Specifications (PS)

4.2.3.9 Finished Product Specifications (FPS)

4.2.4 Procedures for measuring and monitoring

4.2.4.1 Quality Plan (QP)

4.2.4.2 Part Specifications (PS)

4.2.4.3 Finished Product Specifications (FPS)

4.2.4.4 Work Instructions (WI)

4.2.5 Post Market Surveillance

4.2.5.1 Post Market Surveillance Plan (PMSP)

4.2.5.2 Post Market Surveillance Report (PMSR)

4.2.6 Additional documents required for manufacture and assembly of products that are not included as part of the DMR shall be made available and shall be referenced in the DMR documents as applicable.

4.2.6.1 Equipment procedures (set-up, operation, maintenance)

4.3 Changes to the DMR

4.3.1.1 Revisions to the existing contents of the DMR are handled through the Design Change Control process, SOP-6000-001 Design and Development and SOP-5000-001 Document and Records Control.

5 Responsibility:

Role	Responsibility
Engineering	• Coordinating the creation of the DMR during the product development process and transferring the DMR to Operations
Manufacturing	• Revisions to the DMR after product transfer from Engineering
Document Control	• Maintaining current revisions of DMRs per SOP-5000-001 Document and Records Control

6 Referenced QMS Procedures and Work Instructions (not external documents)

The following documents are cross-referenced in this SOP.

SOP-5000-001 Document and Records Control

SOP-6000-001 Design and Development

7 Attachments, Associated Forms, and Associated Controlled Spreadsheets

N/A

8 Revision History

Revision	Effective Date	DCO Number
01	31DEC2019	590
00	16DEC2019	576