PROLLENIUM® MEDICAL TECHNOLOGIES INC	SOP	Doc. #: QA001 Rev. #: 03 Effective Date: DEC 16 2014

Approvals:

Reviewed By	Date	Quality Assurance	Date
	16 DEC 2014		16 Dec 2014

Quality Systems Documentation

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☑ Revanesse ☑ Rev. Ultra ☑ Rev. Pure ☑ Rev. Contour ☑ Rev. Kiss ☑ Revanesse+ ☑ Rev. Ultra+ ☑ Rev. Pure+ ☑ Rev. Contour+ ☑ Rev. Kiss+ ☑ Redexis ☑ Red. Ultra ☑ Redexis+ ☑ Red. Ultra+ ☑ PuraPlas PRP ☑ Dermal Roller SR	☑ Rev. Versa ☑ Rev. Versa+	☑ Revanesse ☑ Rev. Ultra ☑ Rev. Pure ☑ Rev. Contour ☑ Rev. Kiss ☐ Revanesse+ ☐ Rev. Ultra+ ☐ Rev. Pure+ ☐ Rev. Contour+ ☐ Rev. Kiss+	☑ Revanesse ☑ Rev. Ultra ☑ Rev. Contour ☑ Rev. Kiss ☑ Revanesse+ ☑ Rev. Ultra+ ☑ Rev. Contour+ ☑ Rev. Kiss+	☐ Revanesse ☐ Rev. Ultra ☐ Rev. Pure ☐ Rev. Contour ☐ Rev. Kiss ☐ Revanesse+ ☐ Rev. Ultra+ ☐ Rev. Pure+ ☐ Rev. Contour+ ☐ Rev. Kiss+

LEGEND

☐ Document not approved for product (PENDING)

☑ Document approved for product

PROLLENIUM® MEDICAL TECHNOLOGIES INC	SOP	Doc. #: QA001 Rev. #: 03 Effective Date: DEC 16 2014

Approvals:

Reviewed By	Date	Quality Assurance	Date
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Quality Systems Documentation

I PURPOSE

The purpose of this procedure is to describe the structure of Prollenium's Quality Management System Documents and their numbering system.

II APPLICATION

This procedure covers all the documents identified under the Quality Management System and therefore is applicable to all processes executed by Prollenium.

III RESPONSIBILITIES

- Director, Quality Operations, Director Operations or delegate are responsible for initial development of the Quality Management System Documentation
- Director, Quality Operations and Quality Assurance are responsible for continual development and maintenance of Quality Management System Documentation.

IV DEFINITIONS& ACRONYMS

QPM	:	Quality Policy Manual
SOP	:	Standard Operating Procedure
QMS	:	Quality Management System

V PROCEDURE

1.0 General

1.1 As described in Section7.0 of the Quality Policy Manual, Prollenium's QMS Documentation consists of the following.

- Quality Policy Manual (including Quality Policy & Quality Objectives)
- Standard Operating Procedures describing all the processes as required by ISO 13485:2016 (SOPs with Document ID starting with prefix "QA")
- Standard Operating Procedures describing how Prollenium meet the applicable regulatory requirements such as CMDR & Medical Devices Directive 93/42/EEC, June 14, 1993(SOPs with Document ID starting with prefix "QA")
- Standard Operating Procedures describing planning, operations and control activities related to processes and material, product, process specifications (SOPs with Document ID starting with prefix other than "QA")
- Validation Protocols and Reports, Stability Protocols and Reports
- Technical File (for each medical device)
- External documents such as Standards, Codes and Regulations
- Other documents needed for the Quality Management System

- Lab Note Books
- Forms
- Work Instructions
- Job Descriptions
- Specifications
- Quality Records

1.2 The interrelationship of the various levels of documentation is illustrated in Appendix 1 - Fig 1- Quality Management System Document Structure.

2.0 Quality Policy Manual (QPM)

2.1 The purpose of the quality manual is to:

- Define the scope of the quality management system, including details of and justification for any exclusions,
- Outline the structure of the documentation used in the quality management system
- Define the documented procedures established for the quality management system, or reference to them,
- Define and describe the interaction between the processes of the quality management system,
- Define responsibility and authority of management personnel involved in the operation of the quality system, and
- State the company's Quality Policy and Objectives.

2.2 Top Management formulates the Quality Policy and Quality Objectives which are reviewed as required and are discussed annually at the Management Review.

2.3 Document Identification : QPM

QPM - **Q**uality **P**olicy **M**anual

3.0 Standard Operating procedures (SOP)

3.1 The purpose of Standard Operating Procedures is to define systems, assign responsibilities and authorities, and provide instructions for carrying out activities. Operating procedures explain the what, when, who and how for each activity; identify interfaces for the activity; and instruct who should be informed and how the results of the activity should be recorded.

3.2 There are two main groups of SOPs in the documentation system.

3.2.1 Management System SOPs

3.2.2 Operational SOPs

3.3 Management System SOPs describes processes as required under ISO 13485:2016 and how relevant regulatory requirements are met. Operational SOPs describes detailed planning, operational and controlling activities and relevant material, product & process specifications.

3.4 Document Identification - Management System SOPs : QAXXX

XXX - 3 digit sequential number starting 001

3.5 Document Identification – Operational SOPs : AAXXX

AA - Two letter acronym used for location or function
LB: Lab, QC: Quality Control, SF: Safety, QA: Quality Assurance, PR: Purchase, FC: Facility

XXX - 3 digit sequential number starting 001

4.0 Validation Protocols, Stability Protocols

4.1 Validation documents are identified as follows.

VLYYXXX
VL - Validation Document
YY - Last two digits of the Year
XXX - 3 digit sequential number starting 001

4.2 Stability documents are identified as follows.

SBYYXXX
SB - Stability Document
YY - Last two digits of the Year
XXX - 3 digit sequential number starting 001

e.g.: SB13002 – second Stability document assigned in Year 2013.

5.0 Other Reports or Protocols

5.1 Other reports or protocols are identified as follows:

RPTXXX or PRTXXX
RPT - Report
PRT - Protocol
XXX - 3 digit sequential number starting 001

6.0 Technical File and Design History File

6.1 Technical File and design history file are maintained for each type/model of the medical device. Technical files are generated to assist in submissions worldwide.

6.2 It contains or identifies documents defining product specifications, complete manufacturing process and the quality management system requirements including regulatory requirements.

6.3 Documents related to the regulatory requirements are identified as follows.

6.3.1 Documents supporting compliance to the following sections of the Canadian Medical Device Regulation.

- Section 10 to 20 – Safety and Effectiveness Requirements

- Information requested under Section 32 (1) and 32 (4) a) to p) as applicable

6.3.2 Documents supporting compliance to the following sections of the Medical Devices Directives 93/42/EEC
- Essential Requirements set out in Annex I
- Requirements of Annex III, Annex IV and IX (depends on the type of conformity assessment process chosen).

6.4 Document Identification – TFXXX and DHFXXX

TF - Technical File
DHF - Design History File
XXX - 3 digit sequential number starting 001

7.0 Standards Codes and Regulations (External Documents)

7.1 Standards, Codes & Regulations are required as guidance documents to ensure that the products are
- Complying with the applicable regulations (Regulatory Requirement)
- Up to the standard expected by the Customer and Prollenium Medical Technologies (Quality Requirement)

7.2 Director, Quality Operations maintains a library of standards, codes and regulations that are applicable to the program undertaken.

7.3 Director, Quality Operations is responsible for controlling, maintaining and ensuring the latest revision of the documents are available. Form QA002F List of External Documents is maintained and is updated at least twice every year. The changes in the external documents that impact the quality system documents are implemented as soon as practical.

7.4 These documents are identified by the Title, Document ID and Revision # or Edition # as provided by the publisher.

8.0 Lab Notebooks

8.1 Lab notebooks have two groups and are identified as follows
- Lab notebooks for R&D - XX
- Lab notebooks/Logbooks for QC/Commercial - XXXQC-##

XXX - 3 digit sequential number starting 001 (specific number(s)) assigned for a specific logbook function

- 2 digit sequential number starting 01 of a new logbook issued for that logbook function at the beginning of the year or when a logbook is filled

e.g. 001QC-01 - first logbook issued for recording information about the pH meter

9.0 Forms

9.1 Forms are used for recording of data of the monitoring and measurement processes and

information associated with an event.

9.2 Document Identification: AAXXXY

AAXXX	-	SOP Document ID to which the Form is related
Y	-	Document Number starting from A increasing up to Z

10.0 Specifications for Quality Control Materials and Supplies

10.1 Specifications are used to define material requirements for materials used in the QC Laboratory.

10.2 Document Identification: SPXXXXX

SP - Specification

XXXXX - 5 digit sequential number starting 00001

11.0 Purchase Material Specifications for purchased Materials for Medical Device.

11.1 Purchase Material Specifications are used to define requirements for materials and products that are incorporated into the finished product (medical device)

11.2 Document Identification: PNYXXXX

PN - refers to Part Number

Y - refers to a digit that is indicative of what type of material the part is:

PN1####	Raw Material, Packaging Components and items received directly by contract manufacturer
PN2####	Work in Progress (WIP)
PN3####	filled component
PN4####	Finished kit

XXXX - 4 digit sequentially assigned number starting 0001

12.0 Other Documents required by the Quality Management System

12.1 Additional documents that support the Quality Management System, but do not fall under the above mentioned document categories but require approvals and revisions.

12.2 Document Identification: Document Number YYXXX

YY Last two digits of the Year

XXX 3 digit sequentially assigned number starting 001

13.0 Work Instructions

13.1 Work instructions are used to describe in detail some single process of a procedure.

13.2 Document Identification: WIYYX

WI - Work Instruction

YY - last two digits of the procedure
X - sequential number starting from 1

14.0 Job Descriptions

14.1 Job Descriptions are used to describe the responsibilities and qualifications of personnel.

14.2 Document Identification: JDXXX

JD - Job Description

XXX - sequential number starting from 001

15.0 QMS Document Identification

15.1 The documents described in the above sections are controlled according to QA002 Control of Documents Procedure.

15.2 Individual document (except external documents) are identified by
- Document ID
- Revision #
- Effective Date

15.3 Sections 2 to 14 define the Document ID for each type of documents.

15.4 Revision number used are two digit sequential numbers starting from 00 for the initial issue.

15.5 Documents at the draft stage are identified as Draft 1, Draft 2 … etc. Once approved the revision number changed to 00.

15.6 Effective Date reflects the corresponding revision, approved date for issue.

16.0 Quality Records

N/A

VI ASSOCIATED DOCUMENTS

- *MDD 93/42/EEC*
- *CMDR*
- QA002 Control Of Documents

VII APPENDICES

Appendix 1: Fig 1- Quality Management System Document Structure.

VIII PROCEDURE REVISION HISTORY

Rev #	Change Description	Initiator	Effective Date
00	New Document	M.Striez	
01	Change Document CAPA 001	M.Striez	
02	Added in section 1.1: Other documents needed for the Quality Management System Quality Objectives are reviewed as required. Validation stability documents: removed reference to months. Revised section 7.3 to include implementation of changes in external documents. Added section 12 to accommodate other quality system documents not covered anywhere else	Amjad Rana	
03	Added Work Instructions and Job Descriptions in section 1.1 as types of documentation. Added in section 6.1 "Technical files are generated to assist in submissions worldwide". Added section 13 and 14 to include the document identification for Work Instructions and Job Descriptions Added section 15.1 to describe the application of QA002 Control of Documents in this procedure CCN-14044	Amjad Rana	DEC 1 6 2014

Appendix 1:
Quality Management System Document Structure

Quality Policy Manual
(QPM)

Quality System Procedures (QSP) (Management System Procedures)

- Describing all the processes as required by ISO 13485:2016
- Describing how Prollenium meets the applicable regulatory requirements

External Documents
Standards, Codes and Regulations

Quality System Procedures, Work Instructions
-describing planning, Job Descriptions
Operational and control activities of the processes
Other documents required by QMS

Validation
Protocols,
Stability

Protocols and Reports

Technical File for each Medical Device

Specifications

Quality Records
Forms

Lab Note Books