PROLLENIUM®

SOP

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Rev. #: 04
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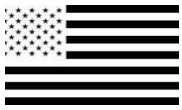
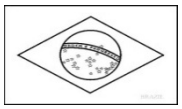
Approvals:

Reviewed By	11 Dec 2017	Quality Assurance	11 Dec 2017
	Date		Date

Control of Quality Records

 Health Canada	 FDA	 EU/CE	 Brazil	 Australia
• Licence 69955 • License 99568 • License 10071	• PMA P160042 • PENDING	• CE 634105 • CE 634109 • PENDING	• 80117580639 • PENDING	• PENDING
☑ 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)

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Control of Quality Records

I PURPOSE

The purpose of this procedure is to define the system used for identification, collection, indexing, access, filing, storage, maintenance and disposition of Quality Records.

II SCOPE

This procedure is applicable to all the Quality Management System records generated within the organization and therefore applicable to all processes.

III RESPONSIBILITIES

- Director, Quality Operations, QC Specialist and other Process Owners are responsible for ensuring that all quality records are indexed, assembled, filed and maintained until disposition is carried out.
- Director, Quality Operations is responsible for contracting disposition activity to a specialist sub contractor and coordinating it.

IV DEFINITIONS

Quality Records:	Records that are required to provide evidence to conformity to requirements and of the effective operation of the Quality Management System
Personal Health Information:	Personal health information (PHI) refers to demographic information, medical history, test and laboratory results, insurance information and other data that a healthcare professional collects to identify an individual and determine appropriate care.
PHIPA:	The Personal Health Information Protection Act, also known as PHIPA is Ontario legislation established in November 2004, which provides a set of rules for the collection, use, and disclosure of personal health information.
HIPAA:	HIPAA (Health Insurance Portability and Accountability Act of 1996) is United States legislation that provides data privacy and security provisions for safeguarding medical information.

Control of Quality Records

V PROCEDURE

1.0 General

1.1 Quality records provide the evidence that product conforms to specification and that the quality system is operated in accordance with documented procedures and that it is effective. The quality records also provide traceability information.

1.2 Quality Records are generated in the process of implementation of the Quality Management System.

1.3 The Quality Records Retention List in Appendix 1 describes in detail the list of Quality Records, the responsible person for maintenance, retention period, and the disposition method.

2.0 Record Identification

2.1 The majority of the quality records are generated through the use of quality record forms, which are identified by the Document # and the Title.

2.2 Forms, when filled out, will include the recording "Date" and/or the specific record identification number such as NCR No.

2.3 Therefore these records are identified by the Title / Doc. # and the Date / Record ID No.

2.4 Other records such as Management Review Meeting minutes are identified by the Title & the Date.

3.0 Storage

3.1 When each record is generated, Director, Quality Operations / QA Specialist / Process Owner, shall ensure that the record is legible and the record is dated and signed as required.

3.2 To ensure that the authorized person signs the record, Director, Quality Operations maintains the "Approved Signature List" which contains the sample authorized signatures/initials.

3.3 Records shall be filed and labeled in a manner to facilitate fast and efficient retrieval. In general, records are filed according to the record ID Number or the date generated.

3.4 Hard copies of the quality records are stored and retained in the file cabinets at the Laboratory or Quality Operations Department in the Main Office. Metal cabinets used for storage prevent damage/deterioration of records. Crucial documents are stored in a fireproof, waterproof cabinet, including all records containing confidential patient-related health information (ie, clinical trial data, customer complaints, etc.) to prevent loss/deterioration and ensure confidentiality.

3.5 Electronic records are stored in the database and backed up as per QA068 Backup and Storage

of Computer Server Electronic Data.

3.6 All quality records are maintained at the Laboratory or at the Quality Operations Department in the Main Office until disposition. Documents and records that are not actively needed may be placed in a qualified, offsite storage facility, such as Iron Mountain. Upon request, documents and records can be retrieved from the offsite storage facility.

Records Containing Personal Health Information (PHI)

3.7 Special storage and handling conditions apply to all records (paper, electronic) that contain Personal Health Information (PHI) to ensure compliance with applicable health information regulations (The Personal Health Information Protection Act (PHIPA), Health Insurance Portability and Accountability Act (HIPAA)). These requirements will ensure that all records containing PHI are protected from deterioration, will remain confidential and will have limited access. PHI records will mostly consist of customer clinical complaint records, such as patient names, patient adverse event information, names of the practitioners treating the patient, and images of adverse events.

3.8 PHI records are not to be photocopied, unless photocopies are needed for the closure of the complaint (ie. sending information to Medical Director) or for auditing purposes (ie. showing auditor examples of complaint records).

3.9 PHI records will have limited access. Only relevant personnel will have access, such as the company executives, QA/RA Director, R&D Director, Medical Director, and QA/RA staff, and receiving Sales Associate.

4.0 References to patient names will only be in the form of First Name, Last Name Initial, to avoid referencing the last name of the patient.
(Ex. John S.)

4.1 PHI records will be kept in a locked, fire-proof, water-proof metal cabinet in the QA/RA Director's office.

4.2 When PHI records are sent (ie. sent to Medical Director for treatment options), the personal aspects of the records will be blacked-out. (ie. any patient-identifying information, including OHIP numbers, doctor's names, illnesses mentioned, the eyes of patient images.) An example of a blacked-out image is shown below:

4.0 Retention Time

4.1 Records retention times are governed by one or more of the following.

- Statutory & Regulatory requirements
- Customer requirements
- Prollenium requirements

4.2 As per ISO 13485:2016 standard, quality records shall be retained for a period of time at least equivalent to the lifetime of the medical device, but not less than 2 years from the date of product release to the customer. Section 55 of CMDR states that the product distribution records shall be maintained the longer of

- Projected useful life of the medical device or
- 2 years after the date of the device is shipped

4.3 The lifetime or the projected useful life of the medical device is considered to be 2 years.

4.4 Prollenium, after considering all the above requirements and other regulatory requirements, has determined the minimum retention period of the quality record as 5 years.

4.5 Electronic records and some specific records as identified in Appendix 1: Quality Records Retention List are maintained indefinitely.

4.6 Records may be retained beyond the established retention times at Management discretion. Such records shall be appropriately labeled, identified and stored.

5.0 Disposition

5.1 Records are disposed of by shredding.

5.3 Records which are scheduled to be destroyed are collected and placed into a disposition bin.

5.4 Director, Quality Operations arranges for a sub-contractor to visit Prollenium for the collection of the records to be disposed, when required.

5.4 Sub contractor then visits Prollenium, collects the records from the disposition bin, shreds them off site and issues a Certificate of Guaranteed Destruction.

5.5 Director, Quality Operations shall maintain the copies of Certificate of Guaranteed Destruction.

VI ASSOCIATED DOCUMENTS

Standard Operating Procedure

- QA001: Quality System Documentation
- QA002: Control of Documents

VII APPENDICES

Appendix 1: Quality Records Retention List

VIII PROCEDURE REVISION HISTORY

Rev #	Change Description	Initiator	Effective Date
00	New Document	M.Striez	
01	Revise Document	M.Striez	
02	Revise Document	M. Striez	
03	Addition of fireproof, waterproof cabinets as storage requirement in Section 3.4, addition of offsite storage in Section 3.6, and revising "finance" department to "accounting" department in Appendix 1 tables. Replaced ISO 13485:2003/2012 references with ISO 13485: current standard. CCN 17133	Colin Hall	
04	Addition to Section 3.4: All records containing confidential patient-related health information (ie, clinical trial data, customer complaints, etc.) are stored in a locked, fireproof and waterproof cabinet to prevent loss/deterioration and ensure confidentiality. Revised Section 3.5: Changed "Electronic records are stored in the database and backed up as per QA002 Control of Documents" to "Backed up as per to QA068 Backup and Storage of Computer Server Electronic Data." Addition of Records Containing Personal Health Information (PHI) Sections 3.7-4.2. Changed ISO 13485: current standard to 2016. Changed retention period to 5 years and updated Appendix 1. CCN17175	Colin Hall	DEC 11 2017

Appendix 1: Quality Records Retention List

Title/Description	Record Maintained By					Retention	Disposition
	Director, Quality Operations	Quality Control Specialist	Shipping Manager	Accounting & HR Department	Executives		
Technical File, Design Dossier (QA049)	X					Indefinite	-
Approved Signature List (QA002)	X					Indefinite	-
Risk Assessment Records (as part of the Technical File, Design Dossier) (QA049)	X					Indefinite	-
Copies of the Customer Contracts / Agreements (QA009)					X	Indefinite	-
Copies of Applications, Certificates, Licenses, and all related submission correspondence to regulatory authorities (QA004)	X					Indefinite	-
All records associated with the Product Design & Development as part of the Design History File (QA049)	X					Indefinite	-
Product Validation Records (QA031)	X					Indefinite	-
Process Validation Records (QA031)	X					Indefinite	-
Copies of Agreements with Suppliers (QA010)					X	Indefinite	-
Product Distribution Record database/Inventory Cards (QA044)			X			Indefinite	-

Control Of Quality Records

Title/Description	Record Maintained By					Retention	Disposition
	Director, Quality Operations	Quality Control Specialist	Shipping Manager	Accounting & HR Department	Executives		
External Audit Reports including Corrective Action Requests (QA019)	X					Indefinite	-
Investigation and root cause analysis reports related to CAR (QA023)	X					Indefinite	-
Records related to Mandatory Problem Reporting Copies of Mandatory (or Voluntary) problem reports submitted to regulatory agencies (QA025) Associated supporting documents such as investigation reports, corrective action plans etc. (QA025) Copies of correspondence (QA025)	X					Indefinite	-
Records related to Product Recall Copies of submissions and correspondence to regulatory authorities associated with product recalls. (QA026) Copies of Recall Notifications (QA026) All other documents associated with each recall (QA026)	X					Indefinite	-
One copy of each superseded / obsolete quality management system documents (QA001)	X					Indefinite	-

Control Of Quality Records

Title/Description	Record Maintained By					Retention	Disposition
	Director, Quality Operations	Quality Control Specialist	Shipping Manager	Accounting & HR Department	Executives		
Copies of Prollenium Order Confirmations (QA009)			X	X		5 Years from the date of the record	Shredding
Customer Purchase Orders (QA009)				X		5 Years from the date of the record	Shredding
Following Quality Records associated with product receipt & verification (QA012)						5 Years from the date of the record	Shredding
Supplier's material / products QC Release Documents (QA027)	X					5 Years from the date of the record	Shredding
QC raw data (QA027)		X				5 Years from the date of the record	Shredding
Prollenium's Test results on representative samples provided by the Supplier (QA010)	X					5 Years from the date of the record	Shredding
Copies of Material/Product Certificate of Release (Certificate of Analysis) (QA027)	X					5 Years from the date of the record	Shredding
Copies of Non Conformance Reports issued to the Suppliers (QA010)	X					5 Years from the date of the record	Shredding

Control Of Quality Records

Title/Description	Record Maintained By					Retention	Disposition
	Director, Quality Operations	Quality Control Specialist	Shipping Manager	Accounting & HR Department	Executives		
Following records associated with shipping finished products Copies of POs issued to Warehouse (QA015) Copies of the Shipping Documents received from Warehouse (QA015) Continuous temperature monitoring records of the finished products (FC024)			X			5 Years from the date of the record	Shredding
Calibration Certificates (QA017)		X				5 Years from the date of the record	Shredding
Audit worksheets / checklists (QA019)	X					5 Years from the date of the record	Shredding
Supplier Quality Audit Reports, Checklists, Work Sheets, Copies of CARS (QA010)	X					5 Years from the date of the record	Shredding
Finished Products Certificate of Release for each lot produced including all QC Records associated with the lot (QA027)	X					5 Years from the date of release	Shredding
Reports of data analysis (QA022)	X					5 Years from the date of the record	Shredding

Control Of Quality Records

Title/Description	Record Maintained By					Retention	Disposition
	Director, Quality Operations	Quality Control Specialist	Shipping Manager	Accounting & HR Department	Executives		
Copies of POs or shipment orders issued to Manufacturing contractor & Warehouse (QA009)			X	X		5 Years from the date of the record	Shredding
Appropriate records of education, training, skills and experience for each employee (QA040)	X					5 Year after termination	Shredding
Approved Supplier List (QA010)	X					5 Years from the date of the record	Shredding
Copies of customer notification correspondence (QA026)	X					5 Years from the date of the record	Shredding
Certificates of Guaranteed Destruction (QA003)	X					5 Years from the date of the record.	Shredding
Copies of Purchase Orders issued to Suppliers (QA009)				X		5 Years from the date of the record	Shredding
Test Reports for the material/products received by the laboratory (QA010)	X					5 Years from the date of the record	Shredding
Customer Requirement review records (QA009)					X	5 Years from the date of the record	Shredding