

**Figure 3: Electronic Folder Structure for a Premarket Review Document for a Class III and IV IVDD Health Canada Licence Application**

- [-] [DeviceName]
  - 01.0-Table of Contents
  - [-] 02.0-Administrative Info
    - 02.1-Application Form & Fee Form
    - 02.2-QMS Certificate
  - 03.0-Pre-Sub. Correspondence
  - [-] 04.0-Additional Class IV Premarket Info
    - 04.1-Cover Letter
    - 04.2-Executive Summary
    - 04.3-Licence Amendments
  - [-] 05.0-Safety & Effectiveness Reqs
    - [-] 05.01-Dev Desc
      - 05.01.01-Intended Use
      - 05.01.02-Clinical Background Info
      - 05.01.03-Intended User
      - 05.01.04-Test Principle-Principles of Operation
      - 05.01.05-Prod Config
      - 05.01.06-Assay Components
      - 05.01.07-Spec
      - 05.01.08-Specimen Collection
      - 05.01.09-Instrument in a Series
      - 05.01.10-Assay Char-Dedicated Assays
      - 05.01.11-Instrumentation Char-Dedicated Instrumentation
    - 05.02-Design Philosophy
    - [-] 05.03-Marketing History
      - 05.03.1-Canada
      - 05.03.2-Intl
      - 05.03.3-Incident Report & Recalls
    - [-] 05.04-Mfging Info
      - 05.04.1-Material Spec
      - 05.04.2-Mfging Process
      - 05.04.3-Mfging Sites
      - 05.04.4-Method of Mfg
      - 05.04.5-QC Activities

- 05.05-Process Validation Studies
- 05.06-Dev Specific Quality Plan
- 05.07-Standards
- 05.08-Sterilization
- ☐ 05.09-Perf. Studies
  - 05.09.1-Software
  - ☐ 05.09.2-Specimen Type
    - 05.09.2.1-Sample Matrix Studies
    - 05.09.2.2-Sample Stability Studies
    - 05.09.3-Metro. Trace. of Cbtr & Ctrl Material Values
  - ☐ 05.09.4-Anal. Perf
    - 05.09.4.1-Anal. Sens
    - 05.09.4.2-Measuring Range
    - ☐ 05.09.4.3-Acc. of Meas
      - 05.09.4.3.i)-Trueness of Meas
      - ☐ 05.09.4.3.ii)-Precision of Meas
        - 05.09.4.3.ii.a)-Rep
        - 05.09.4.3.ii.b)-Repr
    - 05.09.4.4-Anal. Specificity
    - 05.09.4.5-Determination of Assay Cut-Off
    - 05.09.5-Clinical Perf
    - 05.09.6-Near Patient Studies
  - ☐ 05.10-Stbty Studies
    - 05.10.1-Claimed Shelf-Life
    - 05.10.2-In-Use Stbty
    - 05.10.3-Shipping Stbty
    - 05.10.4-Stbty Studies Synopsis
  - 05.11-Risk Analysis & Risk Reduction Measures
  - 05.12-Lit. Studies & Bibliography
- ☐ 06.0-Labeling & Pkging
  - 06.1-Labels & Package Insert
- 07.0-Additional Studies
- 08.0-Appendices