Guidance documents have been prepared to assist in the interpretation of policies and governing statutes and regulations. They are intended to assist in preparing the various device licence applications required when seeking an authorization to sell a medical device product in Canada. Guidance documents are designed to be living documents and will be revised as necessary.

- Cost Recovery
- Good Guidance Practices
- Medical Devices Global Harmonization Task Force
- Medical Devices Guidance Documents

Cost Recovery

- Fees for the Review of Medical Device Licence Applications [2013-06-19]
- How to Pay Fees [2011-02-18]

Medical Devices Guidance Documents

- Consultation on the Proposed Amendments to the Medical Devices Regulations [2014-10-20]
- Guidance Document: Guidance on supporting evidence to be provided for new and amended licence applications for Class III and Class IV medical devices, not including In Vitro Diagnostic Devices (IVDDs) [2012-07-05]
- Notice - Opportunity to be Heard in the Suspension of a Medical Device Licence [2011-12-15]
- Guidance for Manufacturers of Human Immunodeficiency Virus (HIV) Test Kits intended to be used in the Laboratory [2011-12-07]
- Guidance Document - Preparation of the Summary Technical Documentation (STED)-based Class III and Class IV Premarket Medical Device Licence Applications [2011-11-02]
- Guidance Document - Medical Device Applications for Implantable Cardiac Leads [2011-07-25]
- Guidance for the Interpretation of Significant Change of a Medical Device [2011-06-03]
- Guidance Document: Information to be Provided by Manufacturers for the Reprocessing and Sterilization of Reusable Medical Devices [2011-06-01]
- Guidance Document: How to Complete the Application for a New Medical Device Licence/Medical Device Licence Amendment for a Private Label Medical Device [2011-03-29]
- How to Complete the Application for a New Medical Device Licence [2011-03-29]
- Private Label Medical Devices: Questions and Answers [2011-03-29]
- Application for a New Medical Device Licence for a Private Label Medical Device [2011-03-29]
Guidance Document - Private Label Medical Devices [2011-03-15]

Guidance Document: Schedule A and Section 3 to the Food and Drugs Act [2010-10-26]

Bis(2-ethylhexyl) phthalate (DEHP) and Bisphenol A (BPA) - Questions & Answers [2008-08-15]

E15: Definitions for Genomic Biomarkers, Pharmacogenomics, Pharmacogenetics, Genomic Data and Sample Coding Categories [2008-07-29]


Adult Hospital Beds: Patient Entrapment Hazards, Side Rail Latching Reliability, and Other Hazards [2008-03-17]

Bed-related Entrapment and Fall Report Form [2008-03-17]

Notice: Updated Guidance on the Recognition and Use Of Standards under the Medical Devices Regulations [2006-09-22]

Guidance Document: Recognition and Use of Standards under the Medical Device Regulations [2006-09-22]

Keyword Index to Assist Manufacturers in Verifying the Class of Medical Devices [2006-09-14]

Application for a Medical Device Licence Amendment for a Private Label Medical Device [2005-06-01]

Guidance document on the Regulation of Medical Devices Manufactured from or Incorporating Viable or Non-Viable Animal Tissue or their Derivative(s) [2004-07-12]

Guidance for the Labelling of Medical Devices under Section 21 to 23 of the Medical Devices Regulations, Appendices for Labelling: Soft Contact Lenses and Menstrual Tampons [2004-06-12]

Pre-Market Guidance on Bare Cardiovascular Stents [2004-04-28]

Notice to Industry - Licensing Requirements for Inter-dependent Medical Devices [2002-05-07]

Preparation of a Premarket Review Document for Breast Implant and Tissue Expander Applications [2001-02-05]

Preparation of an Application for Investigational Testing - Medical Devices V.3 [1999-02-22]

Preparation of an Application for Investigational Testing - In Vitro Diagnostic Devices (IVDD) V.3 [1999-02-22]

Guidance for the Interpretation of Sections 28 to 31: Licence Application Type [1999-01-12]

Preparation of a Premarket Review Document for Class III and Class IV Device Licence Applications V.2 [1998-10-23]

Guidance for the Labelling of In Vitro Diagnostic Devices - DRAFT [1998-06-24]

Guidance for the risk based classification system - DRAFT [1998-05-04]


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Notice - Release of Proposed GHTF Guidance [2008-08-15]