



Health Canada

Quality Systems ISO 13485

Health Canada requires medical device manufacturers to use a quality system certificate as evidence of compliance to the appropriate regulatory quality system requirement. Health Canada will only accept quality system certificates that have been issued by special third party auditing organizations called Canadian Medical Devices Conformity Assessment System (CMDCAS) recognized registrars. The Medical Devices Regulations do not require importers or distributors of medical devices to have a registered quality system.

The Medical Devices Regulations require class II, III and IV medical devices to be manufactured (class II) or designed and manufactured (class III & IV) under CAN/CSA ISO 13485:2003. There are no regulatory quality system requirements for Class I medical devices. These quality system requirements came into force on January 1, 2003.

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Forms

[Form F201 Change of a Manufacturer's Registration Status](#)

Date: 2006-12-19

[Form F202 Submission of a New or Modified Quality Management System Certificate](#)

Date: 2005-06-15

Guidance Documents

[GD207: Guidance on the content of ISO 13485 quality management system certificates issued by Health Canada recognized registrars](#)

Date: 2007-11-08

[GD210: ISO 13485:2003 Quality Management System Audits Performed by Health Canada Recognized Registrars](#)

Date: 2007-01-31

[GD208/Rev0 - Guidance on the Acceptance of Quality System Certificates before and after January 1, 2003](#)

Date: 2003-01-09

Notices

[Update on transition to the revised versions of ISO 13485 and its impact on the compliance to the quality system requirements of the Canadian Medical Devices Regulations](#)

Date: 2006-03-15

[Final Decision - Cessation of Recognition of Orion Registrar Inc. as a Registrar by Health Canada](#)

Date: 2005-09-19

[Update on the June 10, 2005 Cessation of Recognition of Orion Registrar Inc. as a Registrar by Health Canada](#)

Date: 2005-08-25

[Cessation of Recognition of Orion Registrar inc. as a Registrar by Health Canada](#)

Date: 2005-06-10

[Transition to the revised version of ISO 13485 and it's impact on the compliance to the Quality Sytem requirements of the Canadian Medical Devices Regulations.](#)

Date: 2003-11-20

Policies

[Policy on the Canadian Medical Devices Conformity Assessment System \(CMDCAS\) Quality](#)

Date: 2003-01-09

Recognized Registrars Listing

[List of registrars recognized by Health Canada \(HC\) under section 32.1 of the Medical Devices Regulations \(MDR\)](#)

Date: 2008-03-06