Canada

Latest Updates

- Updated latest information about ML draft guidance on predetermined change control plans, and on UDI.

Software	
Embedded Software	No updates at present.
Software as Medical Device (SaMD)	Aligns with IMDRF risk categorization framework, and hence with MDCG 2019-11
Clinical Decision Support Software (CDS)	Aligns with IMDRF risk categorization framework, and hence with MDCG 2019-11
Change Management Requirements for Software/SaMD	https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/guidance-document-interpretation-significant-change-medical-device.html%23a28
Quality Management System (QMS)	No specific guidance for SaMD QMS, but expects compliance to ISO:13485
Post-Market Management	Aligns with FDA's Digital Health Action Plan

Real World Data/Evidence
No updates at present.

Artificial Intelligence (SiMD & SaMD)	
Machine Learning	Predetermined change control plan guidance - draft https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/pre-market-guidance-machine-learning-enabled-medical-devices.html

Deep Learning	Work in progress for developing regulations on AIML
Best Ethical Practices	Voluntary Code of Conduct on the Responsible Development and Management of Advanced Generative AI Systems
Generative AI	No updates at present.

Cybersecurity
https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/cybersecurity/document.html%23fn1-0-rf

Data Privacy
https://www.canada.ca/en/health-canada/corporate/about-health-canada/activities-responsibilities/access-information-privacy/privacy-impact-assessment-medical-device-problem-reporting-august-2013.html

Labelling	
UDI	Canada has proposed an UDI system in line with IMDRF UDI guidelines. They are expected to publish guidance documents for manufacturers on the implementation of a Unique Device Identification (UDI) system for Medical Devices sold or imported in Canada. https://www.canada.ca/en/health-canada/programs/consultation-unique-device-identification-system-medical-devices-canada.html
Specific Market Requirements	No updates at present.