Health Canada Requirements

Canada operates a **risk-based classification system** according to **Medical Devices Regulations**

🏥 Health Canada

Canadian Department of Health, Medical Device Regulatory Authority

📋 MDEL

Medical Device Establishment Licence

Canadian Device Classification (Class I-IV)

Class I: Low risk, manufacturer's own declaration

Class II: Low-medium risk, license required

Class III: Medium-high risk, license + detailed review

Class IV: High risk, most stringent review

Approval Pathways

- **Standard Pathway:** Standard review process
- **Expedited Pathway:** Expedited review (when specific conditions are met)
- **Agile Licensing:** Flexible pathway for innovative devices such as AI/ML

⏱️ Review Period

Class II: 60 days, Class III/IV: 75 days (target)

🔄 Renewal

MDEL requires annual renewal

💡 **Key Point:** Health Canada has introduced Agile Licensing for AI/ML devices, providing adaptive regulation for continuously learning algorithms