Enabling Reliance Through Data

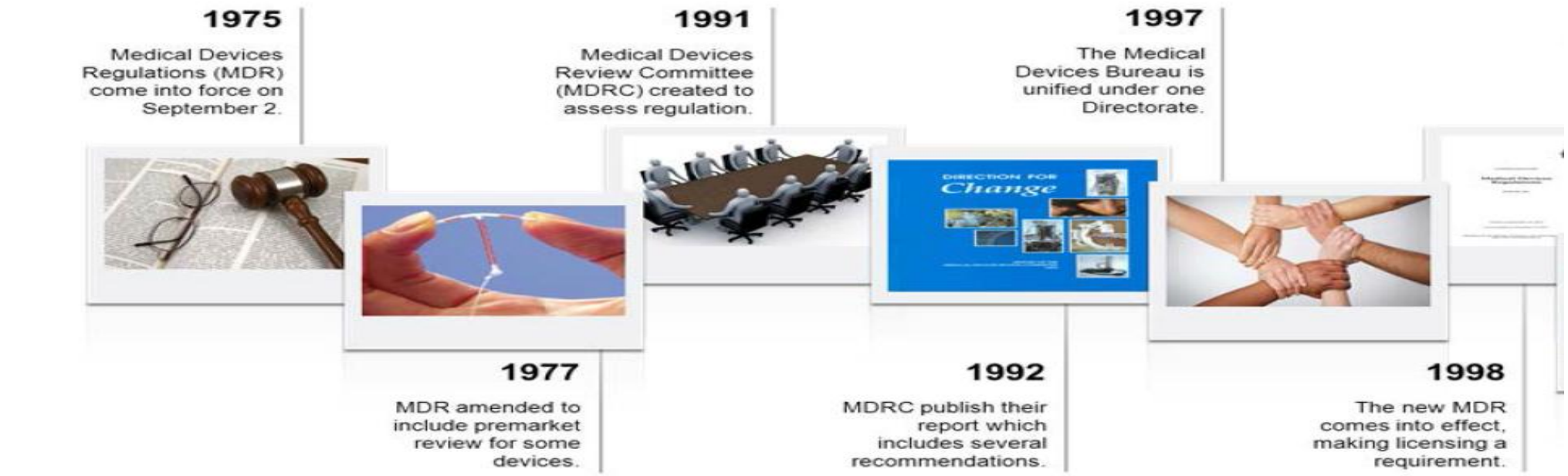
Hands-on Experience - Part I
Health Canada Database

Presented by: Seema Vyas
Director Regulatory Affairs and Quality Assurance, Medtronic Canada

- Capital is Ottawa
- 2nd largest country in the world in area
- 10 Provinces and 3 Territories
- 6 Time Zones
- 2 Official Languages – English and French
- 41.5 M People
  - Represents only 11.8% of US population
  - Represents only 30% of Mexico population

Brief History of the Canadian Medical Device Regulatory Framework

Health Canada



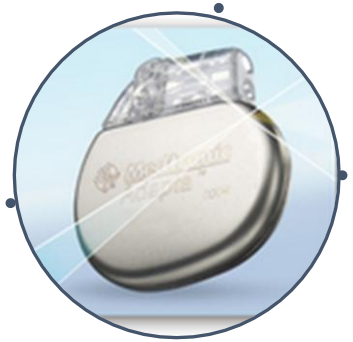
Classification of Medical Devices Section 6 and 7

Lowest to Highest Risk Classification

Class I
Lowest Risk to the body
(Bandages, Scalpel)

Class III
Over 30 days in the body

Class II
Under 30 days in the body



Class IV
Highest risk to the body
(Implantable and/or life sustaining)

Health Canada Regulatory Licensing Requirements

- There are two types of licenses issued by Health Canada for medical devices

Medical Device Licence (MDL)

Issued to

- Manufacturers of class II, III, IV medical devices for human use in Canada

Issued by

- The Medical Devices Directorate (MDD), Health Products and Food Branch, Health Canada

Medical Device Establishment Licence (MDEL)

Issued to

- Manufacturer of Class I devices and importer or seller of Class I-IV medical devices for human use in Canada

Issued by

- Medical Device Compliance and Licensing Unit (MDCLU), Regulatory Operations and Enforcement Branch, Health Canada

Regulatory Licensing Requirements

- Medical Device Licence (MDL)

If a Medical Device can be classified into more than one class, the highest risk class applies.

- Class I device → Establishment licence
- Class II devices → Administrative review
- Class III & IV → Scientific review

- Variation in the level of information included in submissions across risk classes

Application for a Medical Device License
Safety and Effectiveness Required Information
Section 32

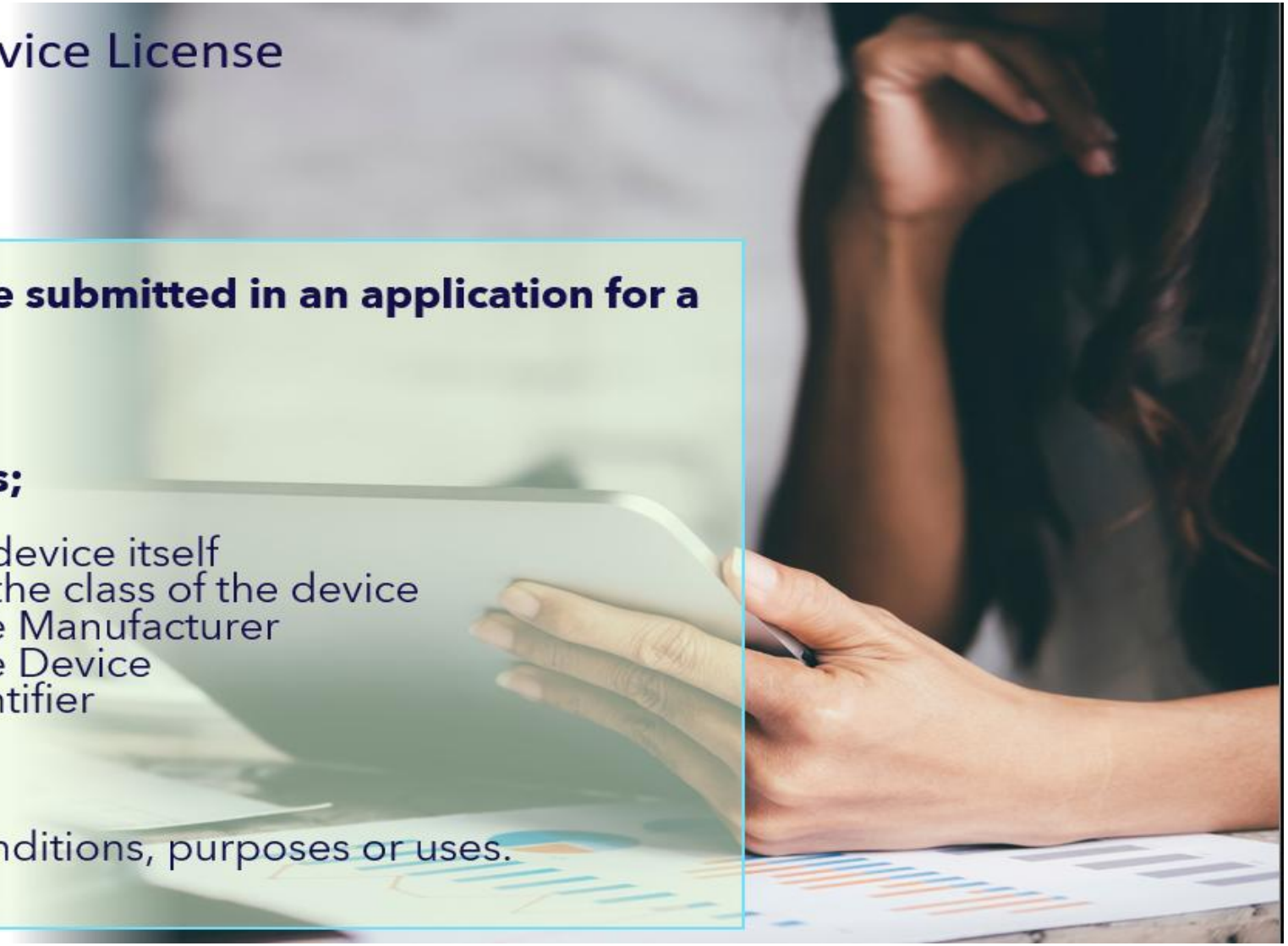
Class III	Class IV

▪ List of standards
▪ **Summary** of preclinical studies
  ▪ Physical and Mechanical Bench Tests
  ▪ Software Verification and Validation
  ▪ Biocompatibility Tests
  ▪ Pyrogenicity
  ▪ Animal Studies
▪ **Summary** of clinical studies
▪ **Summary** of sterilization studies
▪ Packaging
▪ Shelf Life Validation (product and packaging)
▪ Literature/Bibliography
	▪ **Manufacturing and Quality Control**
	▪ **Device Specific Quality Plan**
	▪ **Manufacturing Process and Quality Control Activities**
	▪ **Details for Process Validation Studies**
	▪ **Details for Sterilization**
	▪ **Packaging**
	▪ **Shelf Life Validation**
	▪ List of standards
	▪ **Details** for preclinical studies
	▪ **Details** for clinical evidence
	▪ Literature Studies and Bibliography **(copies)**
	▪ **Risk Assessment**

Major difference between a Class III and a Class IV application is the degree of detail

- Class III applications require outlined summary data;
- Class IV applications requires summaries + full supporting datasets.

Application for a Medical Device License
Amendments to the Device
Section 34



Any proposed changes should be submitted in an application for a Medical Device Amendment.

This applies to:

For class III or IV Medical Devices;

- A significant change to the device itself
- A change that would affect the class of the device
- A change in the name of the Manufacturer
- A change in the name of the Device
- A change in the Device Identifier

For class II devices;

- A change in the medical conditions, purposes or uses.

Health Canada Databases

Medical Devices Active Licence Listing (MDALL)

Medical Devices Establishment Licence Listing (MDEL)

Regulatory Decision Summary

Medical Devices Active Licence Listing (MDALL)

Displays all Class II, III, and IV medical devices currently licensed

Two Types of searches:

Active licences, and

Archived licensed

Active licence search

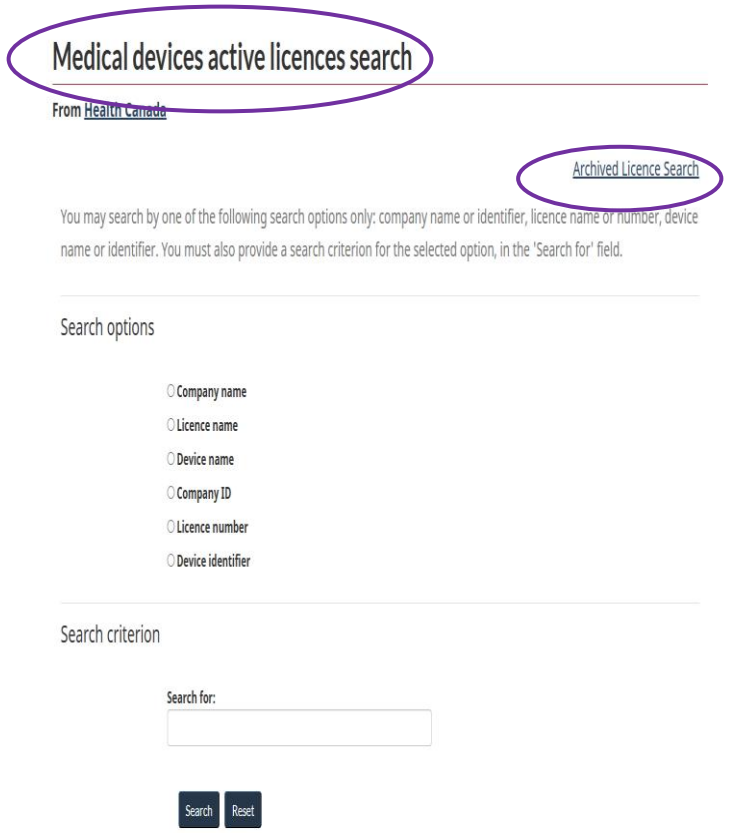
- Company Name
- Licence Name
- Device Name
- Company ID
- Licence Number
- Device Identifier

Archived

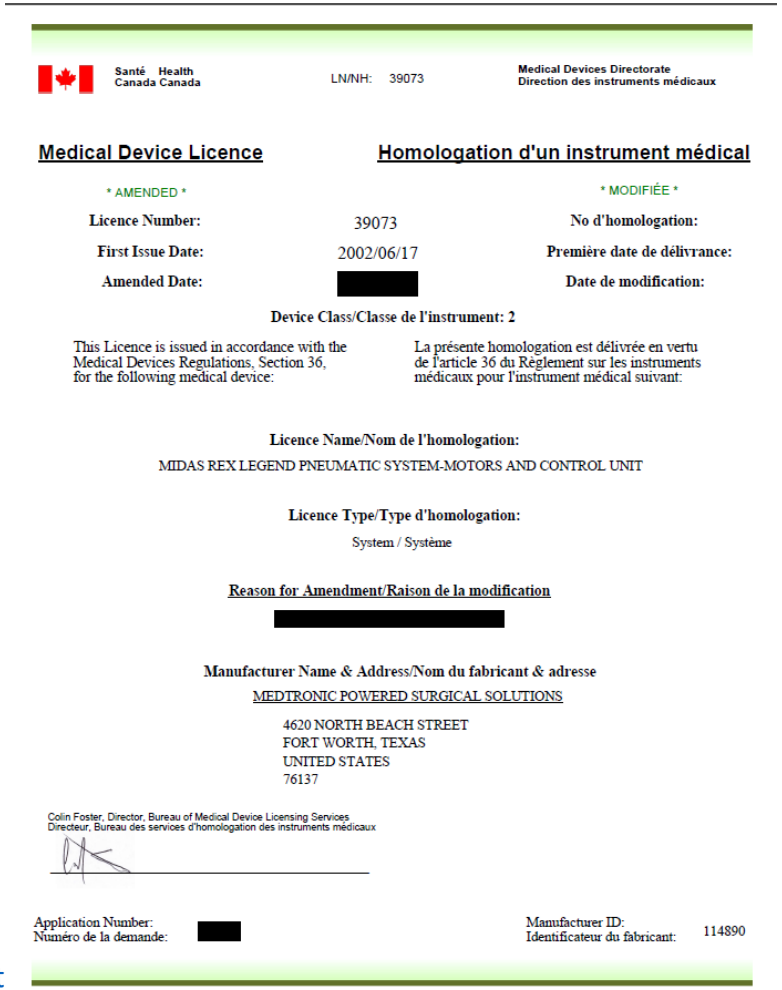
- List of all products ever licensed
- Obsolete products are displayed in red Active products in black
- Licence Number
- Device Name
- Device Identifier
- Displays latest manufacturer and licence name

Note: Does not display Class I devices or devices in clinical trial (Investigational Testing Authorization or special access Authorization
Class I devices do not require a medical device licence and are monitored through Establishment Licensing

Medical Devices Active Licence Listing (MDALL)



https://health-products.canada.ca/mdall-limh/prepareSearch?t



Santé Health Canada Canada LN/NH: 39073 Medical Devices Directorate Direction des instruments médicaux

Medical Device Licence **Homologation d'un instrument médical**

* AMENDED * * MODIFIÉE *

Licence Number:	39073	**No d'homologation:**
First Issue Date:	2002/06/17	**Première date de délivrance:**
Amended Date:	[redacted]	**Date de modification:**

Device Class/Classe de l'instrument: 2

This Licence is issued in accordance with the Medical Devices Regulations, Section 36, for the following medical device:

La présente homologation est délivrée en vertu de l'article 36 du Règlement sur les instruments médicaux pour l'instrument médical suivant:

Licence Name/Nom de l'homologation:

MIDAS REX LEGEND PNEUMATIC SYSTEM-MOTORS AND CONTROL UNIT

Licence Type/Type d'homologation:

System / Système

Reason for Amendment/Raison de la modification

[redacted]

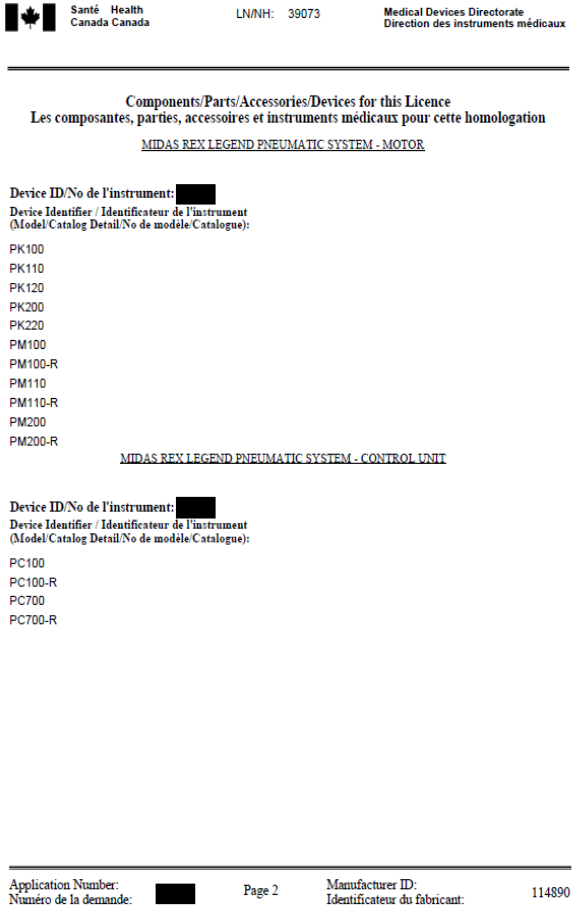
Manufacturer Name & Address/Nom du fabricant & adresse

MEDTRONIC POWERED SURGICAL SOLUTIONS

4620 NORTH BEACH STREET
FORT WORTH, TEXAS
UNITED STATES
76137

Colin Foster, Director, Bureau of Medical Device Licensing Services
Directeur, Bureau des services d'homologation des instruments médicaux

Application Number: Numéro de la demande: [redacted] Manufacturer ID: Identificateur du fabricant: 114890



Santé Health Canada Canada LN/NH: 39073 Medical Devices Directorate Direction des instruments médicaux

Components/Parts/Accessories/Devices for this Licence
Les composantes, parties, accessoires et instruments médicaux pour cette homologation

MIDAS REX LEGEND PNEUMATIC SYSTEM - MOTOR

Device ID/No de l'instrument: [redacted]
Device Identifier / Identificateur de l'instrument (Model/Catalog Detail/No de modèle/Catalogue):

PK100
PK110
PK120
PK200
PK220
PM100
PM100-R
PM110
PM110-R
PM200
PM200-R

MIDAS REX LEGEND PNEUMATIC SYSTEM - CONTROL UNIT

Device ID/No de l'instrument: [redacted]
Device Identifier / Identificateur de l'instrument (Model/Catalog Detail/No de modèle/Catalogue):

PC100
PC100-R
PC700
PC700-R

Application Number: Numéro de la demande: [redacted] Page 2 Manufacturer ID: Identificateur du fabricant: 114890

Medical Devices Establishment Licence Listing (MDEL)

Issued to Class I manufacturers and importers or distributors of all device classes

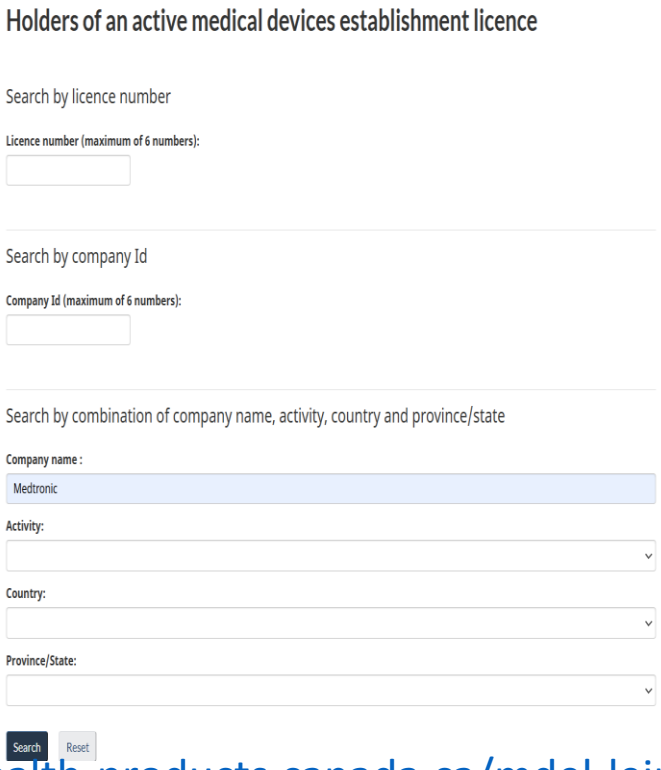
MDEL give Health Canada assurance that:

- Medical devices sold or imported into Canada meet the safety requirements set out in the Medical Devices Regulations
- Procedures are in place to protect the public should a problem with the device be identified

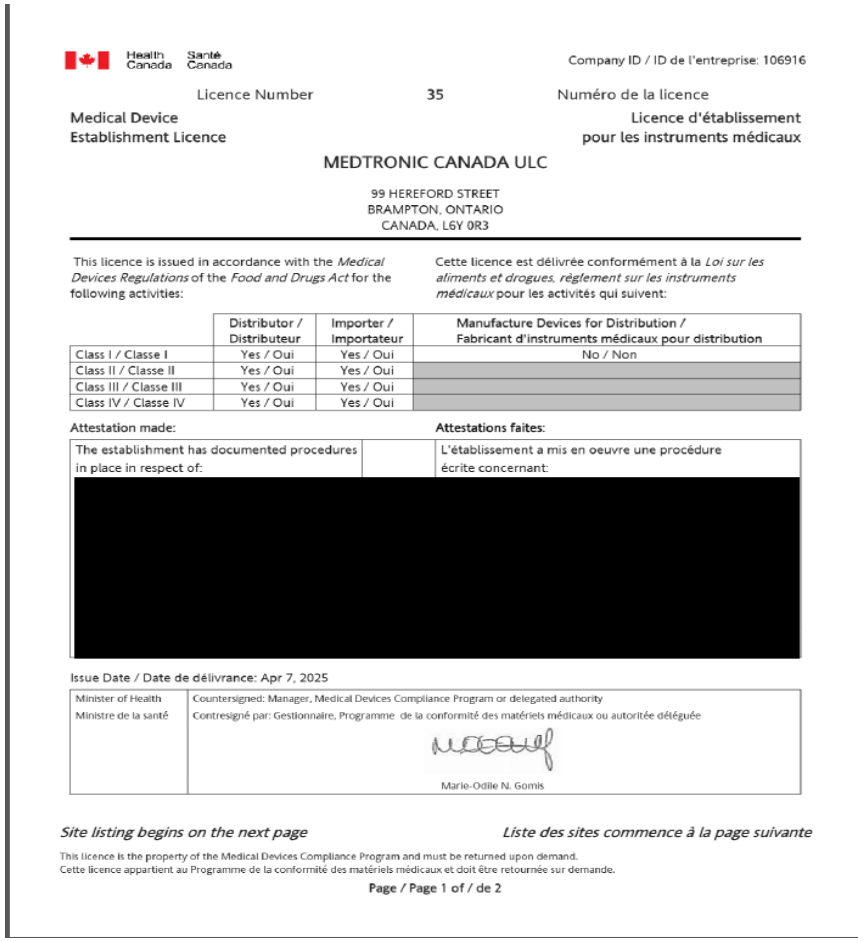
MDEL Listing contains:

- Company ID
- Establishment Licence number
- Company name
- Address
- Authorized activities
- Associated class of device(s)
- Name of the establishment's senior official

Medical Devices Establishment Licence Listing (MDEL)



https://health-products.canada.ca/mdel-leim/index-eng.jsp



Health Canada / Santé Canada

Company ID / ID de l'entreprise: 106916

Licence Number 35 Numéro de la licence

Medical Device Establishment Licence / Licence d'établissement pour les instruments médicaux

MEDTRONIC CANADA ULC

99 HEREFORD STREET
BRAMPTON, ONTARIO
CANADA, L6Y 0R3

This licence is issued in accordance with the *Medical Devices Regulations* of the *Food and Drugs Act* for the following activities:

Cette licence est délivrée conformément à la *Loi sur les aliments et drogues, règlement sur les instruments médicaux* pour les activités qui suivent:

	Distributor / Distributeur	Importer / Importateur	Manufacture Devices for Distribution / Fabricant d'instruments médicaux pour distribution
Class I / Classe I	Yes / Oui	Yes / Oui	No / Non
Class II / Classe II	Yes / Oui	Yes / Oui	
Class III / Classe III	Yes / Oui	Yes / Oui	
Class IV / Classe IV	Yes / Oui	Yes / Oui	

Attestation made: / Attestations faites:

The establishment has documented procedures in place in respect of:		L'établissement a mis en oeuvre une procédure écrite concernant:

[redacted]

Issue Date / Date de délivrance: Apr 7, 2025

Minister of Health / Ministre de la santé	Countersigned: Manager, Medical Devices Compliance Program or delegated authority / Contresigné par: Gestionnaire, Programme de la conformité des matériels médicaux ou autorité déléguée

Marie-Odile N. Gomis

Site listing begins on the next page / *Liste des sites commence à la page suivante*

This licence is the property of the Medical Devices Compliance Program and must be returned upon demand.
Cette licence appartient au Programme de la conformité des matériels médicaux et doit être retournée sur demande.

Page / Page 1 of / de 2

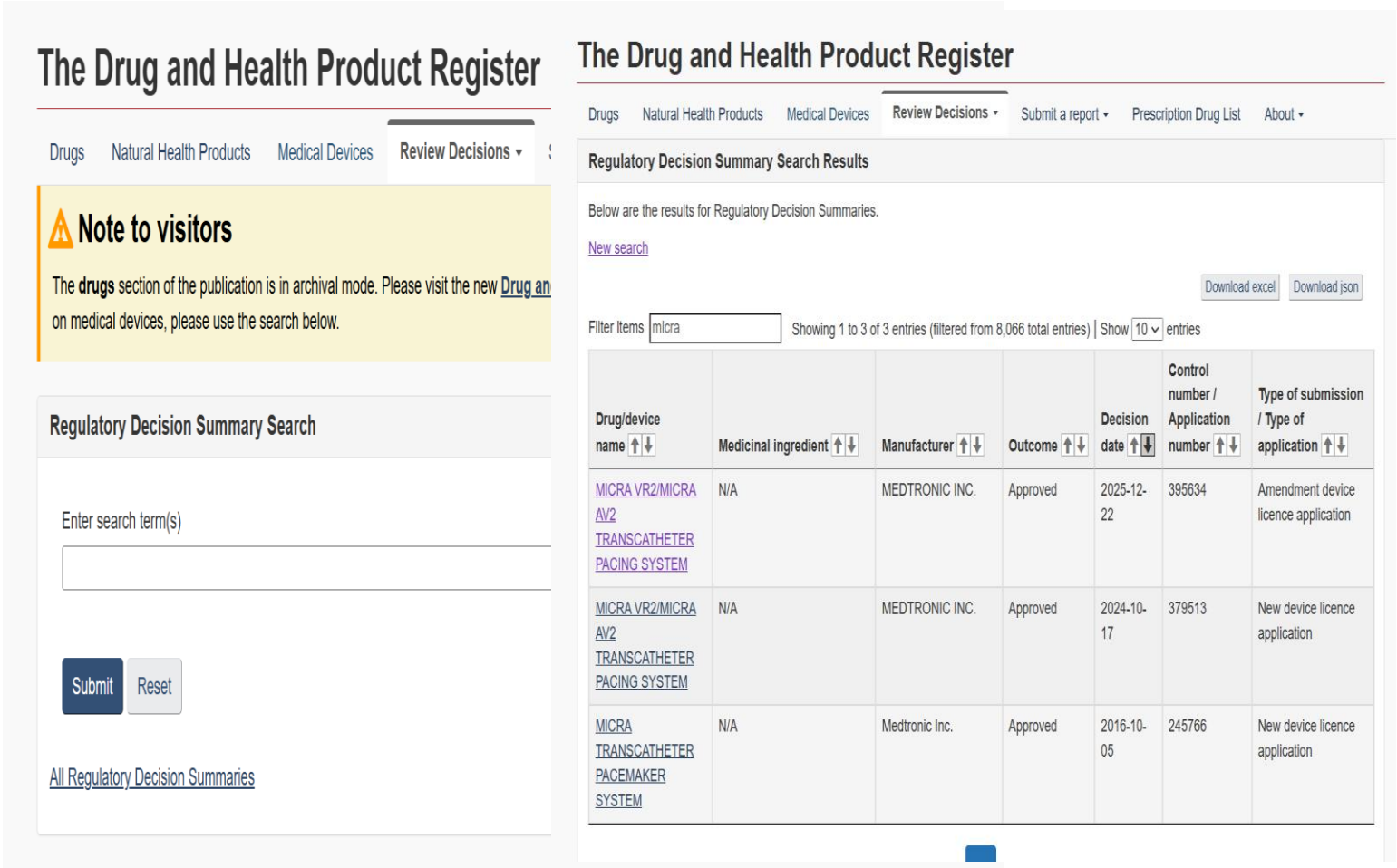
Regulatory Decision Summary (RDS)

Outlines Health Canada's licensing decision for Class III and IV medical device

Includes:

- Purpose of submission
- Summary of intended use
- Reason for the decision
- Manufacturer
- Device name
- Licence number

https://hpr-rps.hres.ca/reg-content/regulatory-decision-summary-result.php?lang=en&term=



Thank you!!

Questions?