Screening

Medical Device Licence Applications

Health Canada Santé Canada

Canada

Bureau of Licensing Services

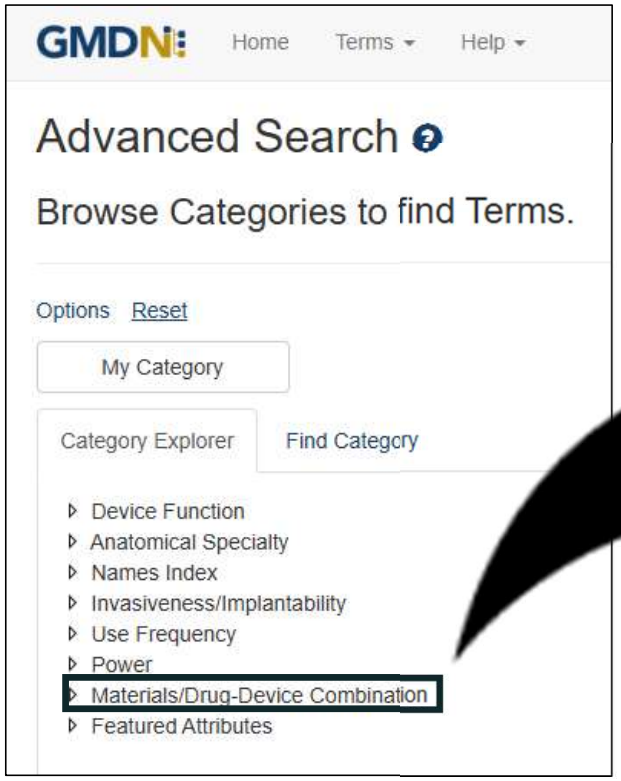
- Records & Information Management
- Application/Licence Management
- Enquiry Management
- Meetings Management
- ATI Coordination

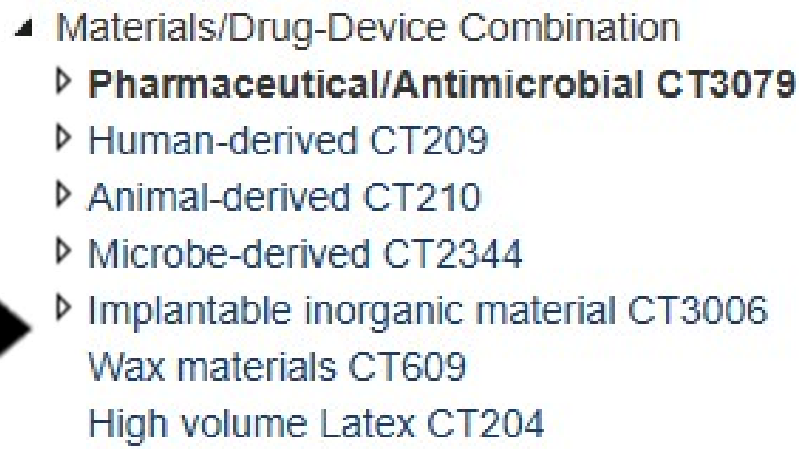
GMDN

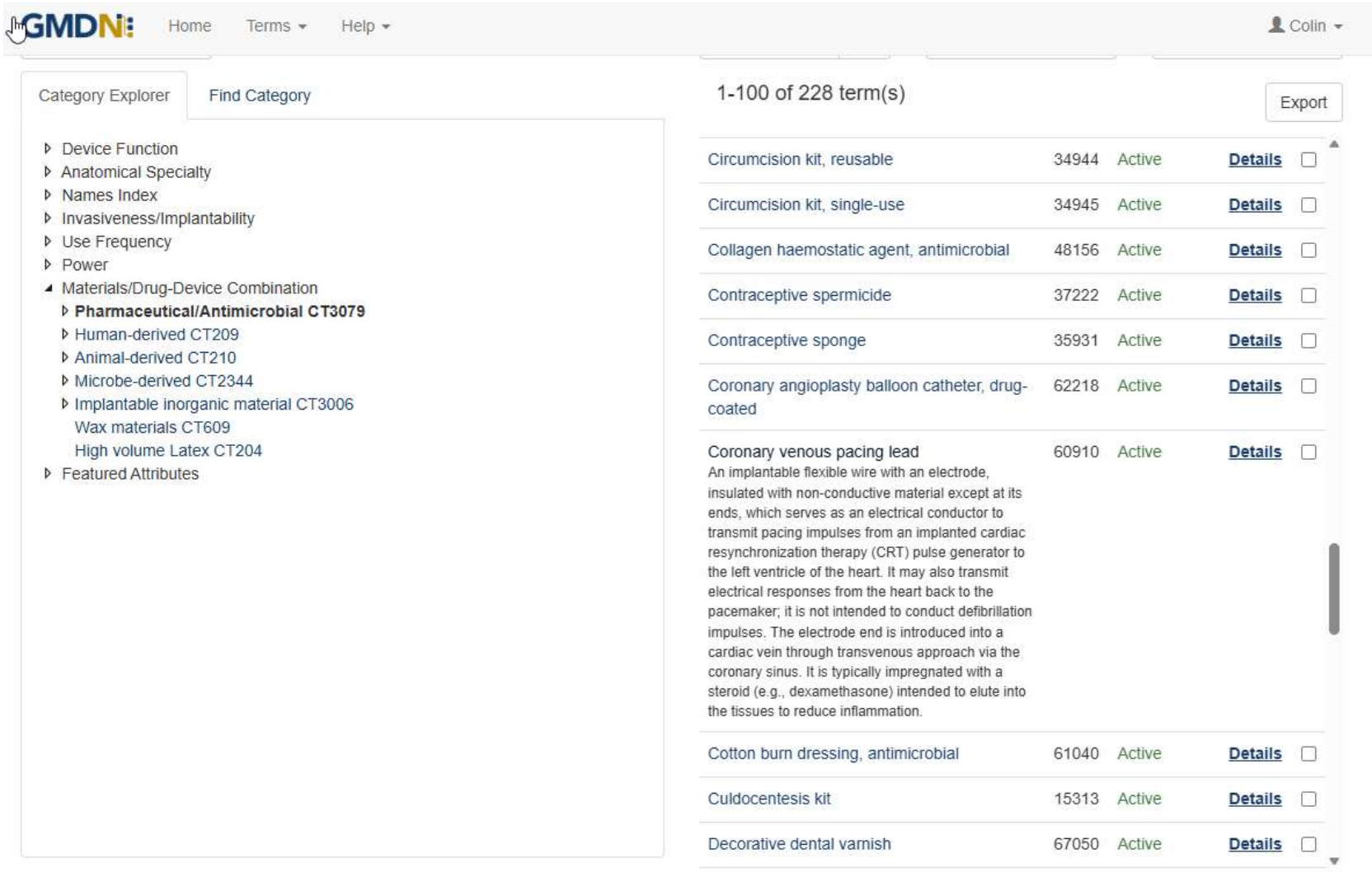
OUR VISION

To provide a single common language for all medical technology, and for it to be adopted by medical device regulators, manufacturers and other participants in healthcare systems worldwide.

Global Medical Device Nomenclature






GMDN
Home
Terms
Help
Colin
Category Explorer
Find Category
Device Function
Anatomical Specialty
Names Index
Invasiveness/Implantability
Use Frequency
Power
Materials/Drug-Device Combination
Pharmaceutical/Antimicrobial CT3079
Human-derived CT209
Animal-derived CT210
Microbe-derived CT2344
Implantable inorganic material CT3006
Wax materials CT609
High volume Latex CT204
Featured Attributes
1-100 of 228 term(s)
Export
Circumcision kit, reusable 34944 Active Details
Circumcision kit, single-use 34945 Active Details
Collagen haemostatic agent, antimicrobial 48156 Active Details
Contraceptive spermicide 37222 Active Details
Contraceptive sponge 35931 Active Details
Coronary angioplasty balloon catheter, drug-coated 62218 Active Details
Coronary venous pacing lead 60910 Active Details
An implantable flexible wire with an electrode, insulated with non-conductive material except at its ends, which serves as an electrical conductor to transmit pacing impulses from an implanted cardiac resynchronization therapy (CRT) pulse generator to the left ventricle of the heart. It may also transmit electrical responses from the heart back to the pacemaker; it is not intended to conduct defibrillation impulses. The electrode end is introduced into a cardiac vein through transvenous approach via the coronary sinus. It is typically impregnated with a steroid (e.g., dexamethasone) intended to elute into the tissues to reduce inflammation.
Cotton burn dressing, antimicrobial 61040 Active Details
Culdocentesis kit 15313 Active Details
Decorative dental varnish 67050 Active Details

10. Medical devices containing drugs	
10.1 Non-IVD devices containing drugs	
If the device contains a drug and is not an IVDD, indicate the Drug Identification Number (DIN) or the Natural Product Number (NPN)and complete the information listed below. If the drug does not have a DIN or NPN, please provide the Drug Establishment Licence (DEL) number of the company from where the drug is sourced.	
Brand/Trade Name of Drug:	DIN/NPN:
Active Ingredient(s):	
Drug Manufacturer:	
DEL Number:	

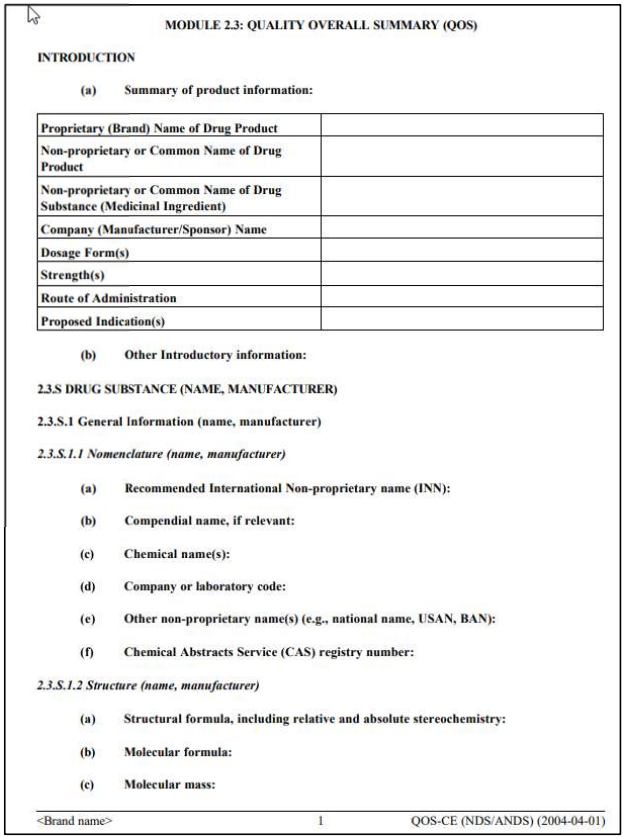
2.04.01 – Comprehensive Device Description and Principle of Operation

k. If the device contains an active pharmaceutical ingredient (API) or drug, an indication of the substance, should be provided. This should include its identity and source, and the intended reason for its presence and its primary mode of action.

Coronary angioplasty balloon catheter, drug-coated

A flexible tube with a drug coating at its distal end designed for percutaneous transluminal coronary angioplasty (PTCA) to dilate an atherosclerotic stenotic coronary artery by controlled inflation of a distal distensible balloon, and to simultaneously release a drug intended to inhibit restenosis. It may also be intended for pre- or post-dilatation of a balloon-expandable stent (not included) in the coronary arteries. It may be available as an over-the-wire (OTW) or a rapid exchange (RX) type, and devices to assist catheterization may be included. This is a single-use device.

QOS



MODULE 2.3: QUALITY OVERALL SUMMARY (QOS)

INTRODUCTION

(a) Summary of product information:

Proprietary (Brand) Name of Drug Product	
Non-proprietary or Common Name of Drug Product	
Non-proprietary or Common Name of Drug Substance (Medicinal Ingredient)	
Company (Manufacturer/Sponsor) Name	
Dosage Form(s)	
Strength(s)	
Route of Administration	
Proposed Indication(s)	

(b) Other Introductory information:

2.3.S DRUG SUBSTANCE (NAME, MANUFACTURER)

2.3.S.1 General Information (name, manufacturer)

2.3.S.1.1 Nomenclature (name, manufacturer)

(a) Recommended International Non-proprietary name (INN):

(b) Compendial name, if relevant:

(c) Chemical name(s):

(d) Company or laboratory code:

(e) Other non-proprietary name(s) (e.g., national name, USAN, BAN):

(f) Chemical Abstracts Service (CAS) registry number:

2.3.S.1.2 Structure (name, manufacturer)

(a) Structural formula, including relative and absolute stereochemistry:

(b) Molecular formula:

(c) Molecular mass:

<Brand name> 1 QOS-CE (NDS/ANDS) (2004-04-01)

6
MONTHS

738
NEW CLASS II APPLICATIONS

426
58% DEFICIENT

Top 3 Deficiencies

1 **Licence Type**
(mainly family type issues)

2 **Device Name Issues**
(mismatch between application form & label)

3 **Risk Class**
(submitting CIII device in CII application or including CI devices)

Licence/Application Type

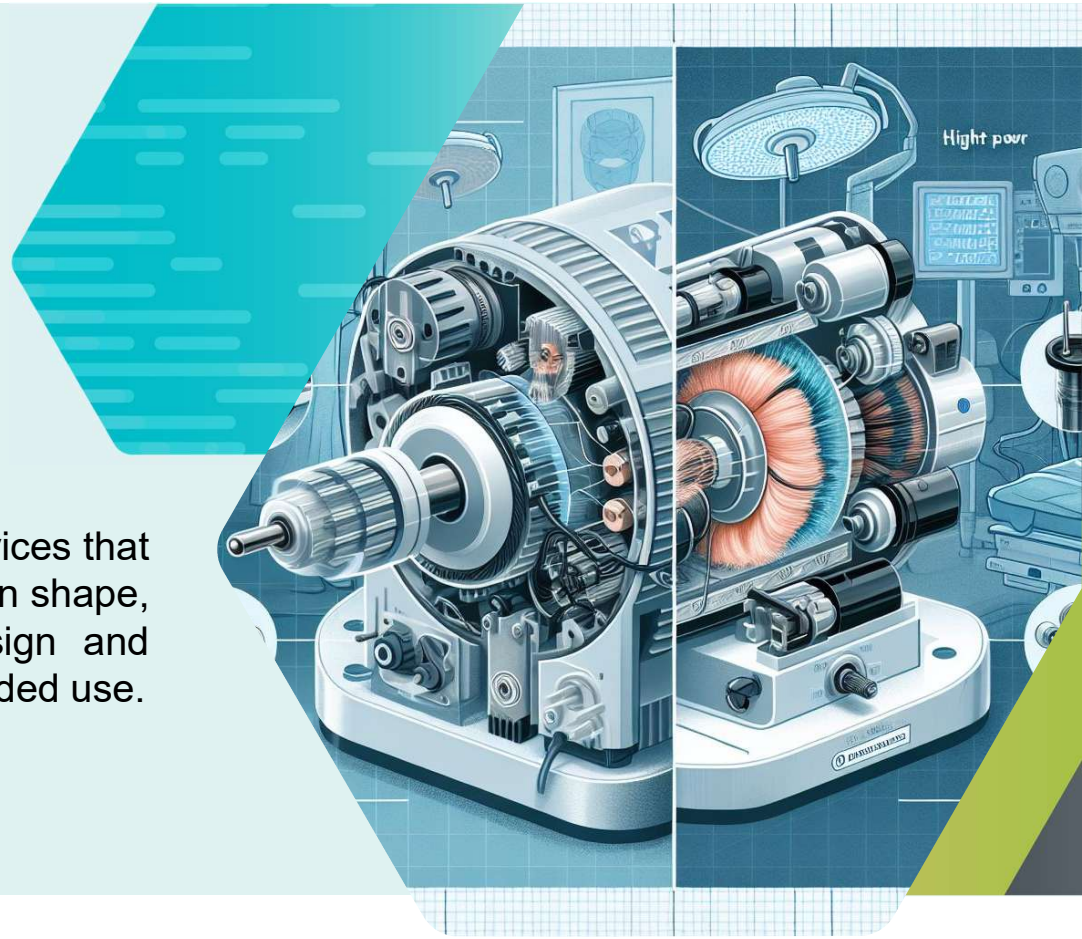
Licence types identify how applicants should package information for Health Canada. The nature in which this information is submitted will dictate how it will be sorted, queued, stored, assessed and registered. Regulatory agencies can operate more efficiently when information is packaged in a consistent, coherent and predictable manner.

new guidance alert

https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/guidance-determining-medical-device-application-type.html

Hint: use GMDN to properly categorize your devices and then use the application type guidance to determine how those different categories should be listed together….or not.

Two electrosurgical instrument models with different motors (AC vs DC)

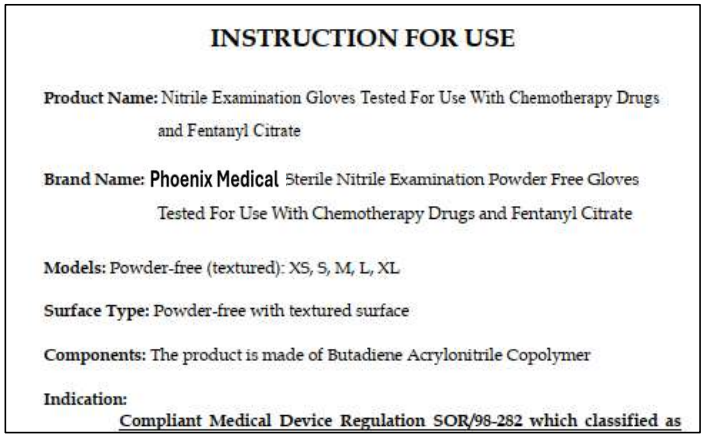


medical device family means a group of medical devices that are made by the same manufacturer, that differ only in shape, colour, flavour or size, that have the same design and manufacturing process and that have the same intended use.

Don’t be so picky about the device name…If it is about the same then it should be fine.

OUTER CARTON

IFU



INSTRUCTION FOR USE

Product Name: Nitrile Examination Gloves Tested For Use With Chemotherapy Drugs and Fentanyl Citrate

Brand Name: Phoenix Medical Sterile Nitrile Examination Powder Free Gloves Tested For Use With Chemotherapy Drugs and Fentanyl Citrate

Models: Powder-free (textured): XS, S, M, L, XL

Surface Type: Powder-free with textured surface

Components: The product is made of Butadiene Acrylonitrile Copolymer

Indication:
Compliant Medical Device Regulation SOR/98-282 which classified as

APPLICATION FORM

Name of device, components, parts and/or accessories as per product label
Non- Sterile, Powder Free Nitrile Examination Glove Tested For Use With Chemotherapy Drugs and Fentanyl Citrate
Non- Sterile, Powder Free Nitrile Examination Glove Tested For Use With Chemotherapy Drugs and Fentanyl Citrate
Non- Sterile, Powder Free Nitrile Examination Glove Tested For Use With Chemotherapy Drugs and Fentanyl Citrate

The review of our Class II application took 8 months. Our application was rejected because Health Canada has determined that our device continues to fit the category of an active diagnostic device by Rule 10(2).


HEALTH CANADA

Hint: go back to first principles: device labelling, risk assessment, schedule 1 of the Medical Devices Regulations

Other topics of conversation…

- software identifiers
- naming of licences
- MDSAP certificates (scopes)
- What else are you interested in?

Questions can be sent to:
meddevices-instrumentsmed@hc-sc.gc.ca