HEALTH CANADA

Program: Medical Devices

LIVINGSTON
Simplify Trade

PGA: Health Canada

Program: Medical Devices

Implementation of the CBSA Single Window Initiative (SWI)

The CBSA assists Health Canada in administering the following legislation at the border: the Canada Consumer Product Safety Act, the Controlled Drugs and Substances Act, the Food and Drugs Act, the Hazardous Products Act, the Radiation Emitting Devices Act, the Pest Control Products Act, as well as regulations made thereunder.

These activities apply to all drugs and devices as defined by the Food and Drug Act, including medical devices.

Under the Single Window Initiative, release requests will be submitted utilizing a new Integrated Import Declaration (IID) that allows for custom brokers to submit and obtain electronic release for goods also regulated by participating departments and agencies.

The Medical Device Regulations require that Class II, III and IV medical devices have a license for each device. Importers of commercial shipments for medical devices must hold an Establishment License (MDEL). However, there are exceptions noted in D19-9-1.

Shipments of medical devices not available in Canada may be authorized for importation through the Special Access Program or the investigational testing provisions of the Medical Device Regulations. These shipments of medical devices may not have a Medical Device License but will be accompanied by a Health Canada authorization letter (Investigational Testing Authorization or Letter of Authorization).

Release requests for Medical Devices products may be provided to the CBSA electronically by submitting an IID. The IID must include the following information:

a. LPCO Type/Authorization Type
b. LPCO Number
c. Exception Process if applicable
d. Brand Name

Note: Under SWI, information requirements will remain the same. There are no additional data requirements for the import process.

Harmonized System (HS) Codes

List of HS codes applicable to goods/substances that may be regulated by Health Canada:
https://www.cbsa-asfc.gc.ca/prog/sw-gu/regcom-marreg/hc-sc-eng.html

Data Element Rationales

The following data element rationales provide additional information of the specific data element requirements required under the Single Window Initiative.

Importer Contact Name	PGAs to contact the importer for IID clarification.
Importer Contact Telephone Number	PGAs to contact the importer for IID clarification.
Importer Contact Email Address	PGAs to contact the importer for IID clarification.
LPCO Type/Authorization Type	Importer must ensure that the product meets the appropriate licensing type to be imported.

LPCO Number	Importer must ensure that the product has a valid licensing number demonstrating its authorization for sale/use in Canada as applicable (DIN, No Objection Letter, etc.).
File	Optional but allows for clearer identification of the product and may ease need for referral.
Exception Process	Importer to indicate exception from the licensing requirements if applicable. For example, importers of medical devices do not require a Medical Device Drug Establishment if they are retailers, clinics, etc. In addition, lymphophematopoietic cells and organs do not need to be processed by a registered establishment.
GTIN Number	Optional but allows for clearer identification of the product and may ease need for referral.
Unique Device Identifier (UDI) Number	Optional but allows for clearer identification of the product and may ease need for referral.
Commodity Type	The Commodity type, declared by the broker/importer, will impact the LPCO Type and LPCO Reference Number.
Manufacture Date	Manufacture date may be provided on the product label. This information will allow for timely recall of goods imported into Canada.
Brand Name	Brand name is required to be on the product label.
Model Number	Optional but allows for clearer identification of the product and may ease need for referral.
Batch/Lot Number	Batch/lot number may be provided on the product label. This information will allow for timely recall postings by having knowledge of the batches/ lots imported into Canada.
Intended Use	The Intended Use, declared by the broker/importer, will impact the LPCO Type and LPCO Reference Number.

Intended Use and Program Conditions for Medical Devices:

Commodities regulated by Health Canada's Medical Devices Program are subject to HS classification control and specific intended use provisions, the following are the applicable intend use conditions:

Intended use	**Description**
HC01	HC - Generic - Human Therapeutic Use
HC02	HC - Generic - Special Access
HC03	HC - Medical Devices - Investigational Testing
HC04	HC - Medical Devices - Custom Made
HC07	HC - Generic – Research & Development
HC29	HC – Generic – Other
HC30	HC – Medical Devices – Trade Shows/Exhibitions

Electronic Commerce Client Requirements Document (ECCRD)

The following table provides the specific rules and conditions associated to each of the data elements for HC Declarations. The data elements are: Mandatory (M), Conditional (C) or Optional (O).

Data element name	PGA element definition	Data element status	Data element rules and conditions
Contact Identification	Importer Contact Name	M	For Health Canada, an importer contact name must be provided for this declaration.
Contact Method	Importer Contact Telephone Number	C	For Health Canada, either an importer contact telephone number or an importer contact e-mail address must be provided.
Contact Method	Importer Contact Email Address	C	For Health Canada, either an importer contact telephone number or an importer contact e-mail address must be provided.
Document Type (Licence, Permit, Certificate, Other)	LPCO Type/ Authorization Type	C	The coded identifier of applicable document types being provided at the declaration level must be provided in this field. Document types provided here must be applicable to all commodities on this declaration. If not applicable to all commodities, please provide the document types at the commodity line level (SG121). Acceptable documents types depend on the Intended Use (SG117 APP) and Canadian Product Category (SG117 PGI). Refer to Appendix A for a listing of document types, intended uses and Canadian product categories.
Document Reference Number	LPCO Number	C	For each document provided at the declaration level, the associated reference number related to that document must be provided. Refer to Appendix B for Reference Numbers.
Document Source Description	File	O	For medical devices being imported for special access, custom made or investigational testing (SG117 APP), it is strongly recommended to provide an image of the Device Letter of Authorization (LOA)/Request as this may improve communication in case of a referral.
PGA Exception Processes	Exception Processes	C	Indicate any exceptional processing required for this transaction. The Health Canada exceptional processing that applies to medical devices: • Medical Device Establishment Licence Exemption Retailers, health care facilities and manufacturers that are eligible for an exemption to the establishment licensing requirement must indicate their status by providing this exception process code. If all commodities on the IID are exempt, provide the exception process code at the declaration level (SG13.RCS). If the exemption applies only to specific commodities on the IID, the exception process code must be reported at the commodity level (SG125.RCS). If this exemption is indicated, the Intended Use Code (SG117 APP) must equal Human Therapeutic Use.

Product Identifier	GTIN Number	O	Medical Devices can be identified through their GTIN GS1 Asset Identifier. Although not required, this information would allow a clearer identification of the product and facilitate communication in case of referrals. The qualifier for GS1 Global Trade Identification Number (GTIN) must be provided in the 7402, 2 field.
Product Identifier	Unique Device Identifier (UDI) Number	O	Medical Devices can be identified through their US FDA Unique Device Identifier (UDI). Although not required, this information would allow a clearer identification of the product and facilitate communication in case of referrals. The qualifier for US FDA Unique Device Identifier (UDI) must be provided in the 7402, 2 field.
Canadian Product Category	Commodity Type	M	A Canadian Product Category must be provided depending on the Intended End-Use Code entered in SG117 APP. Refer to Appendix C for a list of Intended Used and Canadian Product Categories.
Production/ Expiry Date	Manufacture Date	O	It is strongly recommended to provide the date on which the commodity was manufactured.
Commodity Brand Name	Brand Name	M	The brand name of the commodity being imported must be provided.
Commodity Characteristic (Model Name)	Model Number	O	Providing the model, part or catalogue number of the product being imported is strongly recommended. This is the unique series of letters, numbers, any combination of these or a bar code that is assigned to a medical device by the manufacturer to identify and distinguish it from similar devices.
Commodity Lot Number	Batch/Lot Number	O	The batch and or lot number that the manufacturer assigned to the product may be provided.
Intended End Use	Intended Use	M	The intended end-use of the commodity must be provided. Depending on the intended end-use code, additional details are required. Refer to Appendix A for a listing of document types, intended uses and Canadian product categories.
Document Type (Licence, Permit, Certificate, Other)	LPCO Type/ Authorization Type	C	The coded identifier of applicable document types being provided at the commodity-line level must be provided in this field. If applicable to all commodities, please provide the document types at the declaration level (SG9). Acceptable documents types depend on the Intended Use (SG117 APP) and Canadian Product Category (SG117 PGI) provided. Refer to Appendix A: Document types, intended uses and Canadian product categories.

Document Reference Number	LPCO Number	C	For each document provided at the commodity line level, the associated reference number related to that document must be provided. Please refer to Appendix B: Reference Numbers.
Document Source Description	File	O	For medical devices being imported for special access, custom made or investigational testing (SG117 APP), it is strongly recommended to provide an image of the Device Letter of Authorization (LOA)/Request as this may improve communication in case of a referral.

Additional resources

Regulated Commodities:
Reference Code Tables

Legislative References:
The Food and Drugs Act
Medical Devices Regulations

Custom Memoranda:
The Administration of Health Canada Acts and Regulations Relating to Certain Controlled, Prohibited or Regulated Goods.
Memorandum D19-9-1.

Appendix A: Document types, intended uses and Canadian product categories.

Intended Use	Canadian Product Category	Document Type(s)
Human Therapeutic Use	Class 1 Medical Device	Establishment Licence (EL)
	Class 2, 3 or 4 Medical Device	Establishment Licence (EL) AND Medical Device Licence
Investigational Testing	Class 1 Medical Device	None Required
	Class 2, 3 or 4 Medical Device	Device Letter of Authorization (LOA)/Request
Special Access OR Custom Made	Class 1 or 2 Medical Device	None Required
	Class 3 or 4 Medical Device	Device Letter of Authorization (LOA)/Request
Research & Development	All Classes	None Required
Trade Shows/Exhibitions	All Classes	None Required
Other	All Classes	None Required

Appendix B: Reference Numbers

Document Type(s)	Reference Number
Establishment Licence (EL)	Establishment Licence Number
Medical Device Licence	Medical Device Licence Number
Device Letter of Authorization (LOA)/Request	Device Letter of Authorization (LOA)/Request Number

Appendix C: Intended Used and Canadian Product Categories	
Intended Use	**Canadian Product Category**
Human Therapeutic Use	Class 1 Medical Device
	Class 2, 3 or 4 Medical Device
Investigational Testing	Class 1 Medical Device
	Class 2, 3 or 4 Medical Device
Special Access OR Custom Made	Class 1 or 2 Medical Device
	Class 3 or 4 Medical Device
Research & Development	All Classes
Trade Shows/ Exhibitions	All Classes
Other	All Classes

Contact Livingston

Have questions or need help with your SWI imports?
Contact your Livingston client services representative.
Write to us at: **clientserviceCanada@livingstonintl.com** or give us a call at **1-855-225-5544**.