Health Canada Santé Canada

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Application Form for Special Access Medical Devices

Instructions

- Blank fields which are marked as mandatory will result in your application being rejected.
- Completing the form electronically is strongly recommended. If this is not possible, please print clearly (if we cannot make out the information, we cannot process your application). **Handwritten forms may take longer to process.**
- Each health care professional must submit their own application.
- Only one health care professional per form is permitted. Listing more than one will result in rejection.
- Only one manufacturer per form is permitted. Listing more than one will result in rejection.
- Do not use a font or type your signature. **Your application will be automatically rejected.** Wet signatures or digital signatures are accepted.

To submit the completed application, with any supporting documentation

- Submit using our secure submission tool or;
- Fax: 613-957-1596

Privacy notice

The personal information you provide to Health Canada will be collected by the Medical Devices Special Access Program under section 71 (2) of the Medical Devices Regulations and handled in accordance with the Privacy Act.

Why are we collecting your personal information? The information collected will be used for the purpose of assessing requests for access to medical devices under the Special Access provisions of the Medical Devices Regulations. Indirectly identifiable information on the patient (e.g. patient initials or code) will be collected to enable the traceability of the assigned medical device back to the individual.

Will we use or share your personal information for any other reason? In limited and specific situations, personal information may be disclosed without your consent in accordance with subsection 8(2) of the Privacy Act.

What happens if you don't want to provide your personal information? If you choose not to provide the requested information, we will be unable to process your application.

What are your rights? You have the right to access and request a correction and/or notation to your personal information. You also have a right to make a complaint to the Privacy Commissioner of Canada if you feel your personal information has been handled improperly. For more information about these rights, or about how we handle your personal information, please contact the Medical Devices Special Access Program at sap.devices.mdb@hc-sc.gc.ca.

For more information: The collection of your personal information is described in Info Source. Refer to the personal information bank (PIB) HC PPU 430 - Special Access Program - Medical Device.

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Fields marked with an asterisk (*) are mandatory.

Section A : Application Type and Date of Procedure

Select all that apply:

☐ A1. This device is needed for an emergency procedure (the procedure is within 3 days of submitting this application).

☐ A2. I require an anticipatory supply for emergencies when shipping delays would impact patient outcomes [Batch].

☐ A3. I have received verbal authorization from the Special Access Unit on (yyyy-mm-dd):

(This is the date when the procedure is scheduled to take place, not when it took place. You may only enter a past date if you received verbal authorization.)

A4.1. Date of procedure (yyyy-mm-dd)*:	☐ A4.2. The date of procedure is unknown.

A5. Patient Initials or Identifier *:

Section B : Health Care Professional Information

B1. First Name*:	B2. Last Name*:
B3. Title*:	B4. Provincial Licence Number*:

Office Address

B5. Number and Street Name*:

B6. City*:	B7. Province or Territory*:	B8. Postal Code*:

B9. Telephone*:	B10. Telephone (alternative):

B11. Email*:

B12. Email (alternative):

B13. Facsimile:

Section C : Health Care Facility Information

C1. Name of Health Care facility (type full name of facility)*:

Address (of facility, location of procedure)

C2. Number and Street Name*:

C3. City*:	C4. Province or Territory*:	C5. Postal Code*:

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Section D : Unlicenced Device Information

Instructions:

- You may list up to 5 identifiers in the table below.
- Use and attach Health Canada's spreadsheet template to list more than 5 identifiers.
- **Match the labelling as much as possible**. This means matching the name of the device, component or accessory and its catalogue or model number to the manufacturer's labelling and identifying information

D1. Device or system, component or accessory name (e.g. labelled tradename)*:	D2. Identifiers for device, components and accessories (catalogue or model number)*:	D3. Quantity of each catalogue or model number required*:

☐ D4.1 I have previously applied for **any** of these devices, components, or accessories under the Special Access Program.	D4.2 Provide the most recent request number(s):
☐ D5.1 These devices, components, or accessories have previously been licensed in Canada.	D5.2 Provide the licence number(s):

☐ D6. This is a custom-made device and I will attach written directions or design documents for the device (mandatory for custom devices).

☐ D7. The requested device is intended for first-in-human use or has limited experience from early human clinical studies to date.

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Section E : Company Information	
The legal manufacturer is the company that appears on the label of the device. Do not confuse this with the importer or distributor.	The importer or distributor is the company that has been authorized to import or distribute the device on behalf of the manufacturer. In some cases the manufacturer is importing and distributing the devices themselves.
Manufacturer Information*	**Importer or Distributor Information**
E1. Manufacturer Name*:	☐ The manufacturer is the importer or distributor.
	E14. Importer or distributor name:
E2. Contact Name*:	E15. Contact Name:
E3. Contact Title*:	E16. Contact Title:
Company Address	**Company Address**
E4. Number and Street Name*:	E17. Number and Street Name:
E5. City*:	E18. City:
E6. Province, territory or state*:	E19. Province, territory or state:
E7. Postal or ZIP code*:	E20. Postal or ZIP code:
E8. Country*:	E21. Country:
E9. Telephone*:	E22. Telephone:
E10. Email*:	E23. Email:
E11. Facsimile:	E24. Facsimile
E12. Telephone (alternative):	E25. Telephone (alternative):
E13. Email (alternative):	E26. Email (alternative):

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Section F : Medical Rationale

Provide the diagnosis, treatment or prevention for which the unlicenced device is requested and the reasons why this unlicenced device was chosen*.

F1. Provide diagnosis, patient comorbidities and other patient-specific information*:

F2. Treatment (describe why this device was chosen)*:

F3. List the licenced devices considered and provide a rationale as to why these licenced devices would not adequately meet the patient's requirements*.

Device Name*:	**Medical Device Licence (MDL) Number*:** **Search our database for the MDL number)**	**Rationale as to why this licenced device would not adequately meet the patient's requirements*:**

Identify and list the risks and benefits associated with the use of the unlicenced device*.	
F4. Risks*:	F5. Benefits*:
F6. Indicate how the benefits obtained would outweigh the risks*.	

F7. Summarize the known safety and effectiveness information of the unlicenced device*.

Section G : Batch Release Information

If you are requesting a batch release:

G1. Describe the emergency condition requiring treatment:

G2. How many devices are required for 1 month:

Section H : Attestation and Undertaking

Do not use a font or type your signature, **this will result in automatic rejection of your application.** Wet signatures or digital signatures are accepted.

I , _____

(Name of Health Care Professional)*

1. Attest that I am a Health Care Professional who is entitled to provide health services under the laws of the province where the requested device will be used.
2. Undertake to inform the patient, who is to be diagnosed or treated with the device that is the subject of this request, of the risks and benefits associated with its use. If I cannot appropriately inform the patient due to incapacity, I attest that institutional policies will be followed.
3. Attest that the **all** information given is true, correct and complete to the best of my knowledge.
4. Attest that I have specifically reviewed this application, including any supporting material, for consistency and accuracy for the patient or patients to be treated or diagnosed in relation to this request.
5. Attest that I understand that unused devices should be returned to the manufacturer or importer.

Signature*:	Date (yyyy-mm-dd)*: