Health Canada Santé Canada

APPLICATION FORM FOR CUSTOM-MADE DEVICES AND MEDICAL DEVICES FOR SPECIAL ACCESS

OFFICE USE ONLY

Return by e-mail to sap.devices.mdb@hc-sc.gc.ca
Please note that all fields must be completed or the application cannot be processed.

Health Care Professional Information: **(Note: One Application per Health Care Professional)**

Name and Title: Provincial Licence Number: Address: Number and Street: City, Province/Territory:		Postal Code:
Telephone:	Facsimile:	E-Mail:

Health Care Facility Information

Health Care Facility Name: Address: Number and Street: City, Province/Territory:	Postal Code:
Date of Procedure (YYYY-MM-DD):	☐ Check this box if this device is needed for an emergency procedure

Additional Facilities can be listed by inserting additional Health Care Facility fields

Information Regarding Unlicensed Device

Name of Device, Components and Accessories:	
Device Identifier (catalogue or model number):	Quantity of each catalogue or model number required:
☐ Check this box if this is a custom-made device and provide a copy of the health care professional's written direction to the manufacturer giving the design characteristics of the device.	

Manufacturer Information

Manufacturer's Name:		
Contact Name and Title: Address: Number and Street: City, Province/Territory/State:		Postal Code or ZIP Code:
Telephone:	Facsimile:	E-Mail:

Importer (Distributor) Information

Name of Importer or Distributor:		
Contact Name and Title: Address: Number and Street: City, Province/Territory:		Postal Code:
Telephone:	Facsimile:	E-mail:

Canada

Medical Rationale

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

2. List the licensed devices considered and provide a rationale as to why these licensed devices would not adequately meet the requirements of the patient.

Device Name	Medical Device Licence Number [1]	Rationale as to why this licensed device would not adequately meet the requirements of the patient

[1]NOTE: A searchable database of medical devices licensed by Health Canada can be found at: www.mdall.ca

3. Identify and list the risks and benefits associated with the use of the unlicensed device and indicate how the benefits obtained would outweigh the risks.

4. Summarize the known safety and effectiveness information in respect of the device.

5. In the case of a request for Batch Release,

   (a) describe the emergency condition requiring treatment, and

   (b) provide the number of devices required for one month: _____

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Undertaking

Pursuant to Section 71.(2)(i) of the Medical Devices Regulations, health care professionals are required to make an undertaking that they will inform the patient for whom the device is intended of the risks and benefits associated with its use. Please check the following boxes as appropriate and sign below:

☐ I, the Health Care Professional, undertake to inform the patient, _____ ,
Patient's Initials or Identifier
who is to be treated with the device of the risks and benefits associated with the use of this unlicensed medical device.

☐ I, the Health Care Professional, confirm that I have informed the patient, _____,
Patient's Initials or Identifier
who is to be diagnosed or treated with the device of the risks and benefits associated with the use of this unlicensed medical device.

In the case of a batch release request

☐ I, the Health Care Professional, undertake to inform the patients who are to be treated with the device of the risks and benefits associated with the use of this unlicensed medical device.

☐ I, the Health Care Professional, confirm that I cannot inform the patients, who are to be diagnosed or treated with the device of the risks and benefits associated with the use of this unlicensed medical device. I attest that institutional policies will be followed.

Health Care Professional's Signature and Date:_____
Signature Date (YYYY-MM-DD)

Notes

1. In the case of a Batch Release, it is the manufacturer or importer's responsibility to maintain a distribution record in respect of the device in accordance with Sections 52 to 56 of the *Medical Devices Regulations*.
2. Health care professionals are requested to return any unused devices to the manufacturers or importers.

Declaration

I, the Health Care Professional, certify that the information given is true, correct and complete to the best of my knowledge.

Health Care Professional's Signature and Date:_____
Signature Date (YYYY-MM-DD)

Health Care Professional's Name :_____

Return the completed application form with any supporting documentation to the following address by e-mail to sap.devices.mdb@hc-sc.gc.ca

Should there be no alternative, e-fax (or facsimile) can be sent at 613-957-1596. Please verify receipt of your fax by contacting the Programme by phone.

Telephone: 1-613-946-8711
Facsimile: 1-613-957-1596