Instructions for Completing the Application Form for Custom-Made Devices and Medical Devices for Special Access

This document has been prepared to assist health care professionals in preparing the Application Form for Custom-Made Devices and Medical Devices for Special Access. It should be used in conjunction with the Therapeutic Product Directorate Guidance Document entitled *How to Apply for Authorization to Obtain Custom-Made or Special Access Devices* dated March 25, 1998 to determine the full requirements of the Special Access Programme.

Health care professionals may use either this application form or submit a letter containing all the required information as outlined under Part 2, Section 71 of the *Medical Devices Regulations*. When using this form, a response should be provided for each field. If there is insufficient space, a separate page should be attached. Failure to supply complete and adequate information as well as a legible copy will delay the review of the application and result in the issuance of an additional information request or a letter of refusal. Note that the review process is normally **three** working days, i.e. date of receipt to date of authorization, refusal or additional information request. However, health care professionals are requested to apply as soon as they are aware of a surgical procedure which requires Special Access.

The application form is available from the Health Canada web site at http://www.hc-sc.gc.ca/hpb-dgps/therapeut under the Special Access Programme-Medical Devices or by contacting the Special Access Programme at (613) 946-8711 between 8:00 am and 4:30 pm E.S.T., Monday to Friday.

Queries concerning this document should be directed to Special Access Programme, Medical Devices Bureau at tel: (613) 946-8711, fax: (613) 957-1596 or e-mail sap_devices_mdb@hc-sc.gc.ca

The Application Form

Health Care Professional/Applicant Information
Indicate the full name and title of the health care professional/applicant to which all correspondence will be faxed and/or sent. A complete address should include street name and number, city, province, postal code, and telephone and fax numbers including area code.

Health Care Facility Information
Indicate the full name and address of the health care facility at which the device will be used. With the exception of batch releases, the date of surgery should be provided where possible to ensure that authorization is received in time for surgery.

Device Information
Indicate the name of the device as it appears on the product label. Only the device and its components and accessories identified in full will be considered for authorization. With the exception of custom-made devices, device identifier or catalogue number should be specified and provided for each component. For custom-made devices, attach a copy of the written direction to the manufacturer giving the design characteristics of the device. For batch releases, include a rationale as to why multiple devices are required and the quantity sufficient for use in up to **one** month should be requested.

Device Manufacturer
Indicate the name and address of the manufacturer of the device to which the authorization will be issued in the absence of a Canadian importer. A complete address should include street name and number, city, province/state, postal/zip code and country plus the name and title of a contact person and his/her telephone and fax numbers including area and country codes.

Device Importer
Indicate the name and address of the importer of the device to which the authorization will be issued. A complete address should include street name and number, city, province, postal code plus the name and title of a contact person and his/her telephone and fax numbers including area codes.

Medical Rationale

In support of the medical rationale, health care professionals may supply device information including device labelling and published literature etc. along with the application.

Declaration and Attestation

The health care professional/applicant must sign and date the application.