Health Canada Santé Canada

Medical Devices Bureau
Therapeutic Products Directorate
Health Products and Food Branch

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

Phone: (613) 946-8711 Fax: (613) 957-1596

Health Care Professional / Applicant Information

Name and Title:
Address:

Tel. No.: Fax. No.:

Health Care Facility Information

Health Care Facility Name:
Address:

Date of Surgery:

Device Information

Name of Device, Components and Accessories:

Device Identifier (catalogue no/model number)

Quantity of each Catalogue Number Required:

Device Manufacturer

Manufacturer Name:

Contact Name and Title:
Address:

Tel. No.: Fax. No.:

Device Importer

Importer Name:

Contact Name and Title:
Address:

Tel. No.: Fax. No.:

Medical Rationale

Provide the medical conditions for which the device is required and the reasons why this **unlicensed** device was chosen over a licensed device for this particular patient. **In the case of a batch release describe emergency conditions to be treated with requested device as well as an estimate of the quantity required for one month.**

Identify the risks and benefits associated with the use of the device and indicate how the benefits obtained would outweigh the risks

Declaration and Attestation

I,_____, undertake to:
Health Care Professional's Name

(1) inform the patient,_____, who is to be diagnosed or treated with the
Patient's Initials or Identifier
device of the risks and benefits associated with its use;

(2) in the event of an incident involving the device that is related to a failure or a deterioration in the effectiveness of the device or any inadequacy in its labelling or in the directions for use accompanying it and has led to the death or a serious deterioration in the state of the health of a patient, user or other person or, where it is reasonable to believe that such an incident, were it to recur, could lead to the death or a serious deterioration of the state of health of a patient, user or other person, the health care professional will report the incident and the circumstances surrounding it to the Medical Devices Bureau and to the manufacturer or importer of the device within **72 hours**. **Any unused devices will be returned to the manufacturer and that the distribution of the device(s) for patients or uses other than indicated in this authorization is not permitted.**

(3) in the case of Batch release, devices which must be stocked for emergency or urgent use, to submit a declaration form to the Bureau each time a stocked device is used. The request number, device used (name, device identifier or catalogue number, manufacturer and/or importer) and the patient identifier will appear on the signed 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

Return the completed application form along with any supporting documentation to the following address by mail or fax:

Special Access Programme
Device Evaluation DivisionTel: (613) 946-8711;
Medical Devices Bureau Fax: (613) 957-1596
Therapeutic Products Directorate
Room 1605, Statistics Canada Main Building
A.L. 0301H1, Tunney's Pasture
Ottawa, Ontario, Canada K1A 0L2