Health Canada Santé Canada

Medical Devices Bureau
Therapeutic Products Directorate
Health Products and Food Branch

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

RE: Request No: _____

Device Name and Identifier (Catalogue No.):_____

_____

Name and Address of Device Manufacturer or Importer_____

_____

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**.

Health Care Professional's Signature and Date:_____
Signature Date

Return the completed declaration form to the following address by mail or fax:

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