



Form F202 Submission of a New or Modified Quality Management System Certificate

1. Pursuant to subsection 43.1 and subject to section 34 of the *Medical Devices Regulations*, the manufacturer noted below hereby submits a new or modified quality management system.

- a) Certificate number of certificate being replaced:
- b) Certificate number of new or modified certificate:
- c) Indicate change(s) made to certificate identified above in a):

<input type="checkbox"/> Manufacturer's name	<input type="checkbox"/> Scope of Registration	<input type="checkbox"/> Expiry date
<input type="checkbox"/> Manufacturer's address	<input type="checkbox"/> Standard	<input type="checkbox"/> Registrar
<input type="checkbox"/> Locations	<input type="checkbox"/> Issue date	<input type="checkbox"/> Other:.....

d) Licence numbers to which this new/modified certificate applies (enter or attach list):

.....

2. Manufacturer Information

I, the manufacturer holding the certificate identified in 1.a), hereby submit a new or modified version of my quality system certificate in accordance with subsection 43.1 of the *Medical Devices Regulations*.

Name of manufacturer:

Address:

.....

Name of Signing Official (print):

Signature: Date (year/month/day):

Instructions:

Do not send new or modified certificates before their effective date. Mail or fax a copy of this form with an attached copy of your new or modified certificate, including all its attachments and the list required in 1d) if need be, to:

 Section Head, Regulatory and Scientific Section
Medical Devices Bureau

Therapeutic Products Directorate, Health Canada
Room 1605, Statistics Canada Main Building
Tunney's Pasture, Address Locator 0301H1
Ottawa, Ontario, K1A 0K9

Fax to: (613) 957-6345 Attention: Section Head, Regulatory and Scientific Section