Health Canada Santé Canada

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):

☐ Manufacturer's name	☐ Scope of Registration	☐ Expiry date
☐ Manufacturer's address	☐ Standard	☐ Registrar
☐ Locations	☐ Issue date	☐ 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
2934 Baseline Road, Tower B
Address Locator: 3403A
OTTAWA, Ontario K1A 0K9
Fax to: (613) 957-6345 Attention: Section Head, Regulatory and Scientific Section

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