



Canadian Medical Device Regulations:

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

About Emergo Group:

Emergo Group provides regulatory and quality assurance consulting for medical device companies. Specialties include CE Marking / CE Mark, ISO 13485 implementation, FDA 510k submissions, Good Manufacturing Practices (GMP), ISO 14971, cGMP consulting, FDA US Agent and European Authorized Representative services. Since 1997.

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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 (YY/MM/DD):.....

INSTRUCTIONS:

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
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

