



Canadian Medical Device Regulations:

Change of Registration Status Form F201

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 F201
CHANGE OF A MANUFACTURER'S REGISTRATION STATUS**

1. Pursuant to sections 32.3 and 32.4 of the Canadian Medical Devices Regulations and section 5.4.2.1 of Health Canada's Policy on CMDCAS, the registrar noted below hereby informs the Medical Devices Bureau of the following:

- | | | |
|--|---|---|
| <input type="checkbox"/> Suspension | <input type="checkbox"/> Withdrawal
(by registrar) | <input type="checkbox"/> Cancellation
(by manufacturer) |
| <input type="checkbox"/> Expiration
(not renewed) | <input type="checkbox"/> Expiration (delay in renewing)
Estimated date of renewal
(YY/MM/DD)..... | <input type="checkbox"/> Reduction of scope
(*attach copy of new
certificate) |

of the quality management system certificate identified in section 2 of this form.

Provide details:

.....

.....

.....

2. ISO 13485:2003 registration information

Name of registrar:.....

Certificate number:.....

Name of manufacturer:.....

Address:.....

This change to the above certificate is effective as of (YY/MM/DD):.....

Name of registrar's representative:.....

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

Number of pages (including this form):

INSTRUCTIONS:

1. Fill out all applicable fields of this form.
2. Fax form to Health Canada within 15 days of the effective date of suspension, Withdrawal, cancellation, expiration or scope reduction.
3. If this is to notify a scope reduction, attach a copy of the new certificate including all attachments to the certificate.
4. Send this form by fax to (613) 946-6758. Attention: Head, Quality Systems Section, or
5. Email a PDF version of complete form to: ISO13485_CMDCAS_SCECIM@hc-sc.gc.ca