Health Canada Santé Canada

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* (Q90R0), the registrar noted below hereby informs the Medical Devices Bureau of the following:

☐ Suspension

☐ Withdrawal (by registrar)

☐ Cancellation (by manufacturer)

☐ Expiration (not renewed)

☐ Expiration (delay in renewing) Estimated date of renewal (YY/MM/DD):.....

☐ Reduction of scope (*attach copy of new certificate)

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

Provide details (if applicable): .....

.....

.....

2. Registration information

Name of registrar:.....

Certificate number:.....

Name of manufacturer: .....

Address: .....

Standard: ☐ ISO 13488:1996 ☐ ISO 13485:1996 ☐ ISO 13485:2003

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) 954-7666. Attention: Head, Quality Systems Section.

Canada