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 Canadian Medical Devices Conformity Assessment System (CMDCAS)*, the registrar noted below hereby informs the Medical Devices Bureau of the following:

☐ Suspension ☐ Withdrawal / Cancellation ☐ Reduction of scope (*attach copy of new certificate)

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

Provide details: ...……..

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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 or e-mail form to Health Canada within 15 days of the effective date of suspension, withdrawal / cancellation, or scope reduction.
3. If this is to notify of 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 email a portable document format (PDF) version of the completed form to F201@hc-sc.gc.ca