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*, the Auditing Organisation (AO) noted below hereby informs the Medical Devices Directorate of the following:

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

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

Provide details: ...……..

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2. MDSAP ISO 13485:2016 registration information

Name of Auditing Organisation (AO):
……..…….……..…..……..……

MDSAP Certificate number:
……..……..…..……

Name of manufacturer: …….…….……...…….

Address: …….……

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

Name of Auditing Organisation's representative:
……..…….…….

Signature: ……. Date (YY/MM/DD): ….…….

Number of pages (including this form): …….

Instructions:

1. Fill out all applicable fields of this form.
2. 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 MDSAP certificate including all attachments to the certificate.
4. E-mail a portable document format (PDF) version of the completed form to f201@hc-sc.gc.ca