

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

1. In accordance with 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:

Santé

Canada

b) Certificate number of new or modified certificate:

c) Indicate change(s) made to certificate identified above in a):

Manufacturer's name¹ Manufacturer's address¹ Locations

Health

Canada

Scope of registration Standard Issue date Expiry date Registrar Other

1 Changes in a Manufacturer's Name and/or Address may require a Name/Address Change Minor Change Amendment Form

d) Licence, authorization, or application in process numbers to which this new/modified certificate applies (enter or attach list):

2. Manufacturer information

I, the manufacturer holding the certificate identified in 1a), 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 (yyyy/mm/dd):

Instructions:

Mail or email 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 necessary, to:

Medical Devices Directorate Health Canada 11 Holland Avenue Address Locator: 3002A Ottawa ON K1A 0K9

Email: gs.mdb@hc-sc.gc.ca.

Attention: Manager, Quality Systems Section

