MDSAP Transition – Instructions and Clarification

Health Canada has been actively engaging with the medical device industry to support its transition to the new MDSAP program by January 1st, 2019. In light of the comments received, the Department has introduced changes to the transition process announced in notices issued in April and May of 2018.

This communication intends to clarify your obligations with respect to the MDSAP transition and to provide instructions on the documentation that you are required to submit.

Obligation to Transition

All manufacturers of class II, III, and IV medical devices sold in Canada are required to transition to the MDSAP program. Documented evidence of your transition to MDSAP must be submitted to the Medical Devices Bureau by December 31st, 2018 in order to maintain your medical device licences active.

Medical device licences held by manufacturers that fail to demonstrate that they have undertaken the transition to MDSAP will be subject to suspension under section 40(1)(f) of the *Medical Devices Regulations*.

Documentation to Submit

Manufacturers Completing the Transition in 2018

Manufactures undergoing a full MDSAP audit (initial or recertification) in 2018 are expected to submit a copy of a valid MDSAP certificate with a completed form F202 (Submission of New or Modified Quality Management System Certificate) to the Medical Devices Bureau by December 31st, 2018.

Manufacturers Completing the Transition in 2019

The Department recognizes that some manufacturers are facing challenges in scheduling MDSAP audits in 2018, and may not be issued their MDSAP certificate by the transition deadline. Manufacturers that have an initial or recertification MDSAP audit scheduled during the 2019 calendar year are expected to provide the following documents to the Medical Devices Bureau with a completed form F202 (Submission of New or Modified Quality Management System Certificate) by December 31st, 2018:

1. An ISO 13485 certificate issued under CMDCAS valid until at least December 31st, 2018.
2. An ISO 13485 certificate (non-CMDCAS) issued by an MDSAP Auditing Organisation valid from January 1st, 2019 on.

3. Documented evidence that they have made firm arrangements to undergo an initial or recertification MDSAP audit in 2019 (e.g. signed certification agreement, written confirmation from the Auditing Organisation on letterhead, completed form MDSAP AU F0029.1 Medical Device Organization Participation in MDSAP Notification)

   Note: these three documents must be submitted as a single PDF file, in the order listed above, along with a completed form F202, to the following email address: hc.qs.mdb.sc@canada.ca. Please use the following subject line: MDSAP Transition Plan

   - Auditing organisations can issue an ISO 13485 certificate (non-CMDCAS) with a validity period beyond 2018/12/31 based on the existing certification cycle

Once the MDSAP Auditing Organisation issues the MDSAP certificate in 2019, manufacturers are required to submit this certificate to the Medical Devices Bureau with a completed form F202.

Manufacturers Transitioning during a Surveillance Audit in 2018 or 2019

In accordance with the Notice published on April 13, 2018, manufacturers can opt to maintain their existing QMS certification cycle by opting to transition to MDSAP through a surveillance audit. Manufacturers that choose to transition during a surveillance audit are expected to provide the following documents to the Medical Devices Bureau with a completed form F202 (Submission of New or Modified Quality Management System Certificate) by December 31st, 2018:

1. An ISO 13485 certificate issued under CMDCAS valid until at least December 31st, 2018.
2. An ISO 13485 certificate (non-CMDCAS) issued by an MDSAP Auditing Organisation valid from January 1st, 2019 on.
3. An MDSAP Surveillance Audit Confirmation Notification for an MDSAP surveillance audit having taken place in 2018 (this notice should be prepared in accordance with MDSAP AU G0026.1. Surveillance Audit Confirmation Notification Process)

   OR

   Documented evidence that they have made firm arrangements to undergo an MDSAP surveillance audit in 2019 (e.g. signed certification agreement, written confirmation from the Auditing Organisation on letterhead, completed form MDSAP AU F0029.1 Medical Device Organization Participation in MDSAP Notification)

   Note: these three documents must be submitted as a single PDF file, in the order listed above, along with a completed form F202, to the following email address: hc.qs.mdb.sc@canada.ca. Please use the following subject line: MDSAP Transition Plan

   - Auditing organisations can issue an ISO 13485 certificate (non-CMDCAS) with a validity period beyond 2018/12/31 based on the existing certification cycle

Once the MDSAP Auditing Organisation issues the MDSAP certificate, manufacturers are required to submit this certificate to the Medical Devices Bureau with a completed form F202.

Questions or concerns regarding this Notice should be directed to:

Quality Systems Section
Medical Devices Bureau
Health Canada
Holland Cross, Tower A
11 Holland Avenue
Address Locator 3005B
Ottawa, ON
K1A 0K9

Telephone: (613) 948-7194
Email: hc.gs.mdb.sc@canada.ca

For up to date information regarding Health Canada's transition to the MDSAP program, please visit our MDSAP transition website.