Health Canada Santé Canada

NOTICE TO STERILE MEDICAL DEVICE MANUFACTURERS
Health Canada Requirements for Manufacturers Relating to Manufacturing Change to Tyvek® 1073B and 1059B

Purpose

Health Canada has been notified that DuPont is altering their manufacturing process for two grades of Tyvek® (1073B and 1059B). These materials are extensively used in sterile medical device packaging and this change will impact a large number of licenced medical devices.

This notice is intended to communicate Health Canada's approach to managing the change in Tyvek®'s manufacturing process and Health Canada's expectations from manufacturers, including requirements for a modified process for filing a significant change amendment for Class III and IV licences.

Scope

This notice is relevant to any manufacturers of sterile medical devices who hold active Medical Device Licences that use or will use DuPont's new Tyvek® material in the packaging of their currently licenced devices.

Although significant change amendments are only required for Class III and IV medical device licences, the risk assessment and risk management principles described in this notice should be applied to Class II sterile devices to ensure they continue to meet the safety and effectiveness requirements of the *Medical Devices Regulations*.

Health Canada's Approach to Managing the Change in Tyvek®

DuPont is currently undertaking tests to evaluate characteristics of the new Tyvek® material in a variety of packaging configurations and sterilization processes.

Health Canada will be accepting DuPont's test results as a pilot Medical Device Master File and, in cooperation with its international counterparts, will be reviewing the data.

DuPont will be making relevant testing summaries and/or data available to medical device manufacturers.

IMPORTANT NOTES:

- In a number of locations in this notice, reference is made to notification and attestations to be provided to Health Canada. Health Canada will be sending specific communications to each active licence holder. **No notification is required prior to receipt of this communication.**
- No notification is required for Class II licences.
- The approach described here assumes positive outcomes following the review of DuPont's Tyvek® Medical Device Master File. Should issues be identified through the review process, changes to the approach may occur.

For Class III and IV licences, the regulatory requirement for an amendment will be satisfied through a modified process. Specifically, following the review of DuPont's Tyvek® Medical Device Master File, Health Canada will require notification from manufacturers identifying the licences impacted by the change and attesting the configurations and sterilization methods are represented by the testing conducted by DuPont. Standard licence amendment applications may be required in cases where DuPont's testing is not adequately reflective of the package configuration – further details are provided below.

This approach is being taken due to the unique nature and breadth of the use of Tyvek® in medical device packaging and should be considered unique to this case.

Manufacturer's Obligations – Class III and IV Licence Holders

Manufacturers are responsible for the safety of the devices they sell and any changes made to them.

Manufacturers are expected to review the information provided to them by DuPont and assess if it is applicable to the packaging configuration and sterilization process of their device.

- If the DuPont evidence is clearly applicable to their devices, the manufacturer should notify Health Canada, identifying the licences impacted by the change and attesting the configurations and sterilization methods are represented by the testing conducted by DuPont.
- If the packaging configuration and/or sterilization process is not covered by the DuPont testing, the manufacturer is to assess the differences and determine if material or process changes may be reasonably expected to negatively impact device sterility over the stated shelf-life.
    - If the assessment concludes that introducing the new sterile barrier will not significantly impact the packaging's performance, the manufacturer should notify Health Canada, identifying the licences impacted by the change and attesting that the manufacturer's configurations and sterilization methods are sufficiently represented by the testing conducted by DuPont.
    - If there is a reasonable expectation that differences may negatively impact the device sterility over the stated shelf-life, the manufacturer is to submit a Medical Device Licence Amendment Application for a manufacturing change and provide supporting validation using their packaging configuration and sterilization process. This may include sterilization validation, shelf-life validation and package integrity assessments.
- All documentation related to the assessments described above should be available upon request.

Manufacturer's Obligations – Class II Licence Holders

Manufacturers are responsible for the safety of the devices they sell and any changes made to them.

Although notification or licence amendments are only required for Class III and IV medical device licences, the risk assessment and risk management principles described in this notice should be applied for Class II sterile devices to ensure the Class II devices continue to meet the safety and effectiveness requirements of the *Medical Devices Regulations*.

New Licence Applications for Devices Using the new Tyvek®

Requirements for New Medical Device Licence Applications will remain unchanged. Support for the packaging will be required, the form of such support will vary based on the specific circumstances, but may involve reference to DuPont's Tyvek® Medical Device Master File, existing licences, supportive testing, or a detailed scientific justification.

Contact

If you have any questions relating to this notice, please contact the Medial Devices Bureau at mdb_enquiries@hc-sc.gc.ca or 613-957-7285.