

24th November 2014.

Re: DuPont™ Tyvek changes

Dear Regulatory Professional,

In June 2011, the DuPont™ Medical and Pharmaceutical Protection Team announced that they will be transitioning DuPont™ Tyvek® 1073B and Tyvek® 1059B to manufacturing lines that use their latest flash-spinning technology. The rationale for this change is to ensure greater continuity and flexibility of supply to meet the growing demand for healthcare packaging around the globe.

In preparation for this transition, DuPont has prepared studies designed to demonstrate the functional equivalence of Tyvek non-wovens manufactured under an upgraded flash-spinning process to Tyvek products manufactured by the present process.

Upon successful completion of the proposed tests (outlined in their protocol, revised addendum dated 12-Jul-11) and demonstration of satisfactory evidence that the performance (process capability, sterility, package integrity, etc.) of Tyvek products from the upgraded process is functionally equivalent to existing Tyvek products, DuPont will document and publicise the approved study conclusions including the range of sterilisation processes and conditions covered.

In accordance with their specific change assessment process, risk management process and as required by the appropriate sterilisation standards, manufacturers must:

- review the change in Tyvek
- assess DuPont information
- have documented records of their change review including
 - review of risks,
 - rationale for accepting the protocol conclusions for their application or
 - Identification of further testing required.

Such records will need to be included in the respective medical device design files.

The expectation is that legal manufacturers who hold CE Certification with NSAI:

1. For Class I sterile, IIa and IIb devices the implementation of the change will be reviewed at the next scheduled Notified Body Surveillance audit.

2. For Class III devices the change should be submitted under a CE product significant change notification. NSAI confirms that consideration will be given to the work carried out by DuPont in relation to the general aspects of the material equivalence when reviewing the significant change notification.

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Manufacturers of Class III devices should contact NSAI on medical.devices@nsai.ie, to schedule the review. To ensure the continued validity of your CE certification, the notification and approval of significant change must be made prior to commercialization of devices utilizing the new Tyvek

Based on the DuPont Tyvek Medical Packaging Transition Project (MPTP) Executive Overview dated 02-Oct-14, Tyvek 1073B & Tyvek 1059B produced on the newer manufacturing lines are anticipated to be fully commercialised in Q3, 2015.

A handwritten signature in black ink that reads "Susan Murphy".

Susan Murphy
Risk Management Officer
NSAI.

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