DQS Medizinprodukte GmbH

To whom it may concern,

Frankfurt a. M.,
09.09.2014

DuPont Medical and Pharmaceutical Packaging will be transitioning Tyvek® 1073B and 1059B styles for medical packaging applications to manufacturing lines using the latest Tyvek® manufacturing technology.

In preparation of this transition, DuPont presented to **DQS Medizinprodukte GmbH (CE 0297)** a status update of the currently available project documentation. The objective of the project is to demonstrate the functional equivalence of Tyvek® non-wovens manufactured under an upgraded flash-spinning process to Tyvek® products manufactured by the present process. The studies are detailed in a document entitled *"Addendum to the Protocol for Transition of the Medical Device Industry to Tyvek® Manufactured Using an Upgraded Spinning Process"* accepted by the US FDA on February 20, 2013, Health Canada and by various European Notified Bodies. **Considering the information provided by DuPont and noting** the position of the US FDA, Health Canada and the other notified bodies that published a statement on the transition project **DQS Medizinprodukte GmbH (CE 0297)** considers the protocol to be an applicable set of tests in order to demonstrate the functional equivalence.

Upon successful completion of the proposed tests 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 as well as in accordance with sterilisation standards, manufacturers will have to review the change in Tyvek® and 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.

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It expected that the Legal Manufacturers who hold CE Certification for Class Is, IIa and IIb will assess DuPont information within their specific change control process in accordance with sterilisation standards and implement the change through their Quality System, which will be reviewed at the next scheduled Notified Body Audit.

For Legal Manufacturers who hold CE Certification for Class III devices it is expected that the impact of the change will be assessed, the applicability of DuPont's information on the product, rationale for accepting the protocol conclusions for their application and/or identification of further testing required. This should be submitted to the relevant Notified Body under a significant change notification. It is expected that consideration will be given to the work carried out by DuPont by Notified Bodies in relation to the general aspects of the material equivalence when reviewing the significant change notification.

Yours sincerely,
DQS Medizinprodukte GmbH

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