



August 2015

DuPont™ Tyvek® Medical Packaging Transition Project (MPTP)

An open letter to the medical packaging industry,

As promised, this letter is to notify you that DuPont has completed the submissions of all Regulatory Reports for MPTP through 1-Year Real-Time Aging to the following:

- U.S. FDA
- Health Canada
- BSI Assurance UK, Ltd.
- LNE/G-MED
- SGS United Kingdom Limited
- TÜV Rheinland LGA Products GmbH
- TÜV SÜD Product Service GmbH

These confidential Regulatory Reports include both individual Cell Reports and Summary Reports after the following study time points:

- Pre- and Post-sterilization
- 1-Year Accelerated Aging
- 3-Year Accelerated Aging
- 5-Year Accelerated Aging
- 1-Year Real-Time Aging
- Executive Summary Report

We are in the process of conducting face-to-face meetings with these regulatory bodies to review all results to date and respond to their questions.

Also, as promised, both the **1-Year Real-Time Aging Industry Summary Report** and the **5-Year Accelerated Aging Industry Summary Report** are now available at www.areyouready.tyvek.com.

In addition, we have created an **Industry Executive Summary Report** that summarizes the Industry Summary Reports for all study time points through 1-Year Real-Time Aging. The Industry Executive Summary Report is also now available at www.areyouready.tyvek.com.

MDMs with devices sold in Europe that require a submission to their Notified Body (Class III, some IIb) need to have specific conversations with their Notified Body regarding referencing and documenting the DuPont Regulatory Reports or Industry Summary Reports in their submissions.

Completing these regulatory submissions and posting these Industry Summary Reports are major milestones in our mutual journey toward Functional Equivalence and industry transition to Tyvek® 1073B and Tyvek® 1059B made on our newer assets. We are extremely proud of the results accomplished to date and the engagement we continue to see from customers around the world.

We expect U.S. FDA affirmation of Functional Equivalence in September 2015 and are on track to begin commercial sales in October 2015. It is essential that you continue to move forward and complete your change control processes, risk assessments and regulatory submissions to the Notified Bodies so that you are able to accept Current and Transition Tyvek® products interchangeably.

As always, we will continue to provide multiple ways for you to stay informed, including our website, www.transition.tyvek.com; our global webcasts; face-to-face seminars; or you can request an individual meeting with a member of our global team.

Thank you for your business and ongoing engagement.



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