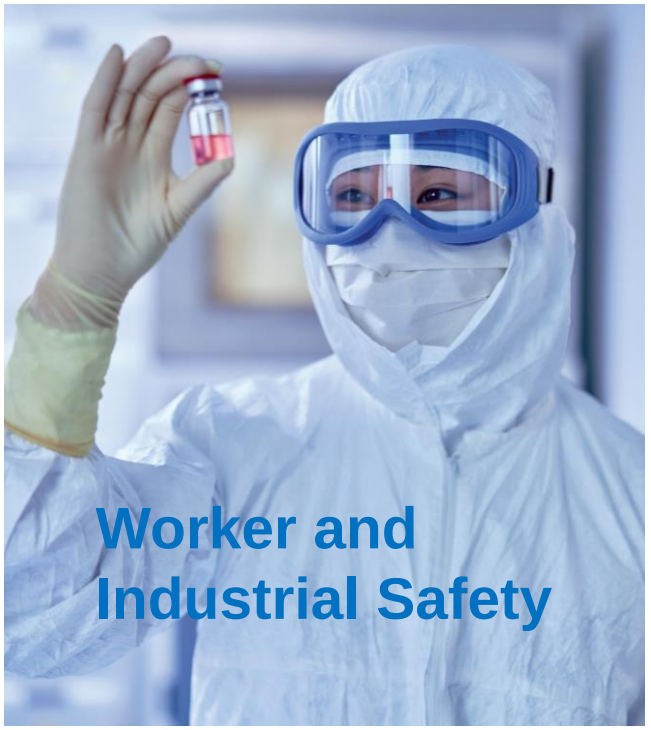
DuPont's history in the sterile packaging market

Regulatory Excellence as a Strategic Pillar for Sustainable and Successful Healthcare Business

Thierry Wagner
Global Director Regulations & Standards*
DuPont Safety, Healthcare

* as of 1st of October 2019

DUPONT Tyvek



Worker and Industrial Safety

Enabling innovations for:

› Personal protective equipment
› Infection and disease protection
› Thermal and electrical protection
› Clean processes

DUPONT Kevlar | Nomex | Tyvek | Tychem

3

DuPont™ Tyvek®

Healthcare Packaging Applications
DuPont Safety - Healthcare

DUPONT™

The Role of Medical Packaging for Sterile Devices

Enable sterilization, protect, maintain sterility, allow for aseptic presentation

… a key element to minimize the risk of nosocomial infections

DUPONT

DuPont™ Tyvek® for Healthcare

Recognized as the standard of excellence in sterile packaging since its introduction in 1972. The unique structure of Tyvek® gives it inherent advantages over other materials. Used for

- Medical Devices
- Combination Products
- Pharmaceutical Processing

DUPONT

Global Medical Device Regulations and Standards

Global medical packaging requirements:

- **Design** to minimize the **risk**
- **Qualification** of materials
- **Design & Process Validation**

And maintaining the packaging process and changes under control

Applying International Standards:
EN ISO 11607 – Parts 1 & 2 "*Packaging for terminally sterilized medical devices"* developed by ISO TC198/WG7 and other standards like EN ISO 13485, EN ISO 14971, EN ISO 10993…

DuPont™ Tyvek® Medical Packaging Manufacturing Locations

Manufacturing Location by Style:

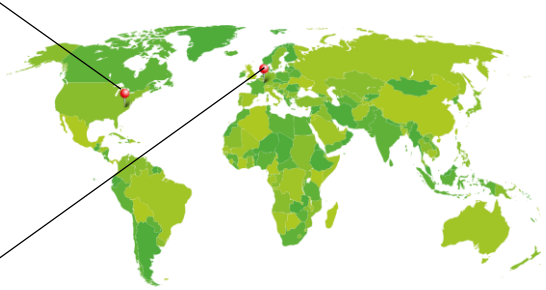
Tyvek® 1073B
Tyvek® 1059B
Tyvek® 40L

Richmond, VA

Since 2015

Tyvek® 2FS™

Luxembourg



The Challenge

A materials science company makes a manufacturing change, impacting a material used in a highly regulated industry.

How can this be accomplished without triggering a revalidation?

DUPONT

Medical Packaging Transition Project

The DuPont™ Tyvek® Medical Packaging Transition Project (**MPTP**) is a plan to transition Tyvek® 1073B and Tyvek® 1059B to the latest flash-spinning technology to help ensure greater continuity and flexibility of future supply.

Goal: demonstrate **functional equivalence** in an effort to help mitigate requalification

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Regulatory bodies involved in the MPTP

ca. 90% of Global Medical Device Market

U.S. FDA/CDRH
Health Canada
CFDA
Japan MHLW
BSI Assurance UK Ltd
LNE/G-MED
SGS United Kingdom Limited
TüV Rheinland LGA Products GmbH
TüV SÜD Product Service GmbH

DQS Medizinprodukte GmbH
NSAI Inc.
AMTAC Certification Services Ltd
Intertek SEMKO AB
Dekra Certification GmbH
Dekra Certification B.V.

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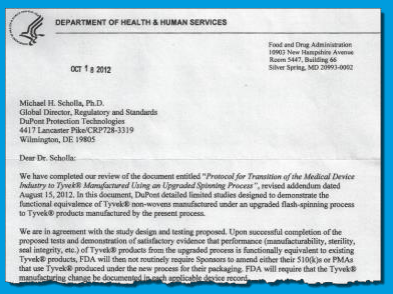


DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Room 5447, Building 66
Silver Spring, MD 20993-0002

OCT 1 8 2012

Michael H. Scholla, Ph.D.
Global Director, Regulatory and Standards
DuPont Protection Technologies
4417 Lancaster Pike/CRP728-3319
Wilmington, DE 19805

Dear Dr. Scholla:

We have completed our review of the document entitled "*Protocol for Transition of the Medical Device Industry to Tyvek® Manufactured Using an Upgraded Spinning Process*", revised addendum dated August 15, 2012. In this document, DuPont detailed limited 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.

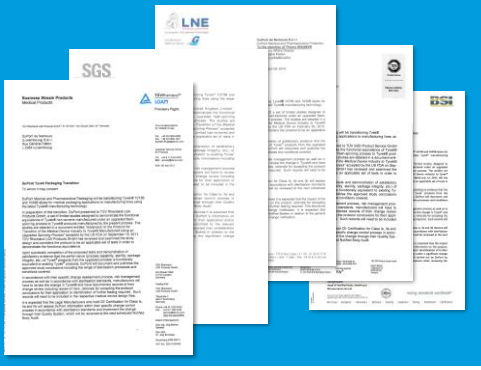
We are in agreement with the study design and testing proposed. Upon successful completion of the proposed tests and demonstration of satisfactory evidence that performance (manufacturability, sterility, seal integrity, etc.) of Tyvek® products from the upgraded process is functionally equivalent to existing Tyvek® products, FDA will then not routinely require Sponsors to amend either their 510(k)s or PMAs that use Tyvek® produced under the new process for their packaging. FDA will require that the Tyvek® manufacturing change be documented in each applicable device record.

The U.S.FDA

Oct 18, 2012: *We have completed our review of the documentation….we are in agreement with the study design and testing proposed…. FDA will not routinely require Sponsors to amend either their 510(k)s or PMAs*

EU notified bodies

A consortium of 5 NBs issues a common letter with their acceptance and guidance on how to file the change



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Medical Packaging Transition Protocol Testing

Transition Protocol Test Matrix

		Style	Pouches and Bags						Form-Fill-Seal					Rigid Trays								
EO	Coated	1073B	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
EO	Uncoated	1059B	22	23	24	25	26	27															
Gamma	Coated	1073B	28		29		30		31		32		33		34		35		36		37		38	39
Gamma	Uncoated	1059B	40		41		42																
Electron-beam	Coated	1073B							43		44		45										
Electron-beam	Uncoated	1059B	46		47		48																
EO	Coated	1059B							49		50		51										
EO	Uncoated	1059B	52	53	54	55	56	57	58		59		60										

Each cell represent a US FDA approved medical device manufactured using qualified designs and validated processes

60 + 18 packaging applications over the entire supply chain

DuPont → Sterile Packaging Manufacture → Medical Device Manufacturer → Steriliser X **78**

Preparation of > 100,000 samples

Lab Testing

Pre-sterilization

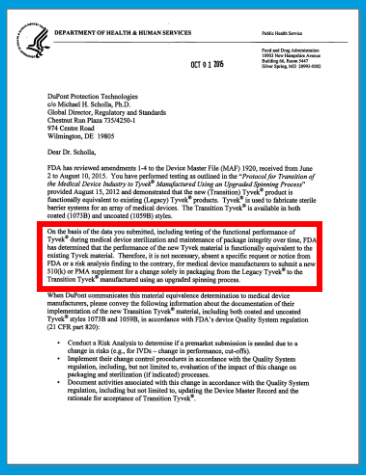
Post-sterilization

- Accelerated Aging 1, 3, 5, 10 years Equivalents
- Real Time Aging 1, 3, 5, 10 years

Reporting

www.areyouready.tyvek.com

Functional Equivalence Affirmed – 1 Oct 2015



DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

OCT 0 1 2015

DuPont Protection Technologies
c/o Michael H. Schella, Ph.D.
Global Director, Regulatory and Standards
Chestnut Run Plaza 735/4250-1
974 Centre Road
Wilmington, DE 19805

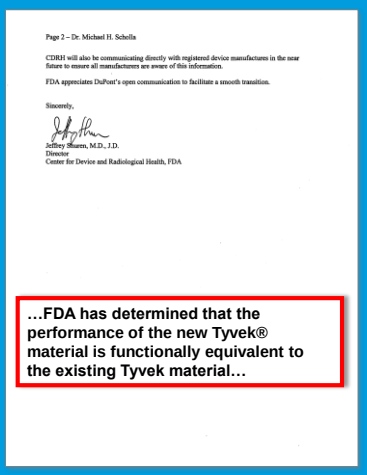
Dear Dr. Schella,

FDA has reviewed amendments 1-4 to the Device Master File (MAF) 1920, received from June 2 to August 10, 2015. You have performed testing as outlined in the "*Protocol for Transition of the Medical Device Industry to Tyvek® Manufactured Using an Upgraded Spinning Process*" provided August 13, 2012 and demonstrated that the new (Transition) Tyvek® product is functionally equivalent to existing (Legacy) Tyvek® products. Tyvek® is used to fabricate sterile barrier systems for an array of medical devices. The Transition Tyvek® is available in both coated (1073B) and uncoated (1059B) styles.

On the basis of the data you submitted, including testing of the functional performance of Tyvek® during medical device sterilization and maintenance of package integrity over time, FDA has determined that the performance of the new Tyvek material is functionally equivalent to the existing Tyvek material. Therefore, it is not necessary, absent a specific request or notice from FDA or a risk analysis finding to the contrary, for medical device manufacturers to submit a new 510(k) or PMA supplement for a change solely in packaging from the Legacy Tyvek® to the Transition Tyvek® manufactured using an upgraded spinning process.

When DuPont communicates this material equivalence determination to medical device manufacturers, please convey the following information about the documentation of their implementation of the new Transition Tyvek® material, including both coated and uncoated Tyvek® styles 1073B and 1059B, in accordance with FDA's device Quality System regulation (21 CFR part 820):

- Conduct a Risk Analysis to determine if a premarket submission is needed due to a change in risks (e.g., for IVDs – change in performance, cut-offs).
- Implement their change control procedures in accordance with the Quality System regulation, including, but not limited to, evaluation of the impact of this change on packaging and sterilization (if indicated) processes.
- Document activities associated with this change in accordance with the Quality System regulation, including but not limited to, updating the Device Master Record and the rationale for acceptance of Transition Tyvek®.



Page 2 – Dr. Michael H. Schella

CDRH will also be communicating directly with registered device manufacturers in the near future to ensure all manufacturers are aware of this information.

FDA appreciates DuPont's open communication to facilitate a smooth transition.

Sincerely,

Jeffrey Shuren, M.D., J.D.
Director
Center for Device and Radiological Health, FDA

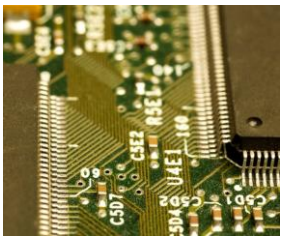
…FDA has determined that the performance of the new Tyvek® material is functionally equivalent to the existing Tyvek material…

Functional equivalence became the basis to transition without systematic revalidation all over the world*

*transition to be filed as a significant change under EU regulations

Key Future Challenges in the Healthcare Industry

Medical Device Regulation



Big Data

Affordable healthcare for aging population

Sustainability

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