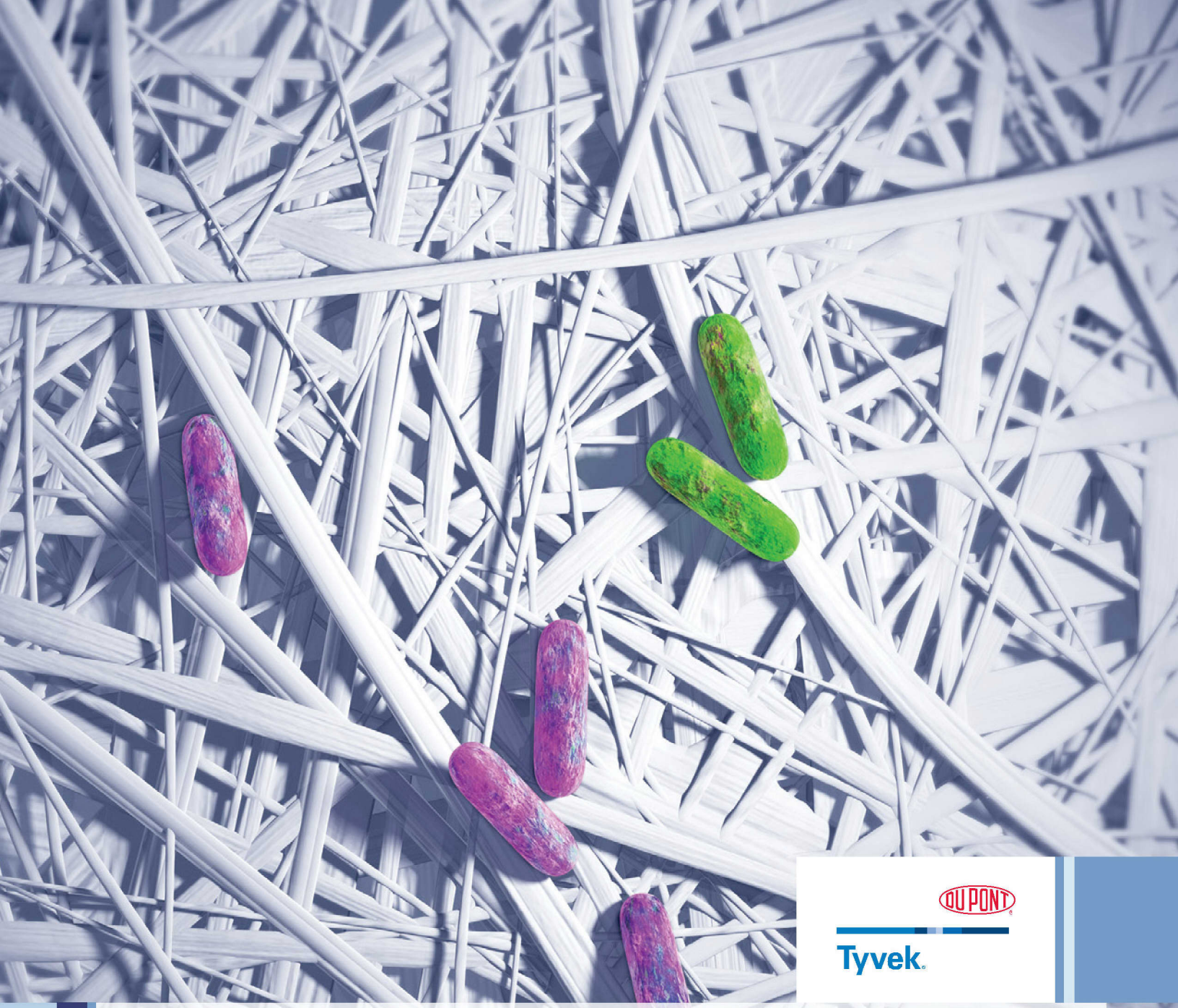

DUPONT Tyvek

DUPONT™ TYVEK®
COMPLIANCE TO ISO 11607-1:2006

CONTENTS

INTRODUCTION

DuPont™ Tyvek® spunbonded olefin is intended for packaging of terminally sterilized medical devices. To guide the medical device manufacturers and sterile packaging manufacturers in their selection and use of packaging, the International Standards community has promulgated the ISO 11607-1:2006 *Packaging for terminally sterilized medical devices Part 1: Materials, sterile barrier systems and packaging systems and ISO 11607-2:2006 Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembly processes.*

As the producer of Tyvek® for medical and pharmaceutical packaging, DuPont Medical and Pharmaceutical Protection has compiled documentation which demonstrates the compliance of Tyvek® with the materials portion of the ISO 11607-1:2006 standard. This will allow medical device manufacturers and sterile packaging manufacturers to focus on the package material production, final package design qualification, and the device package process validation portions of the standard. The compliance is supported by a number of DuPont Technical Information Documents (TIDs) which contain the necessary experimental data. In this preamble, the documents are described and their applicability to the various sections of the ISO 11607-1:2006 document are explained. The TIDs, which cover material testing for sterile barrier systems, can be used to demonstrate packaging compliance to this standard. Much of the information in the TIDs is presented in the *DuPont Technical Reference Guide for Medical and Pharmaceutical Packaging* located at http://www2.dupont.com/Medical_Packaging/en_US/tech_info/index.html

The product characteristics of Tyvek® include:

- Outstanding porous microbial barrier
- Strength to weight ratio
- Moisture resistance
- Inertness to most chemicals
- Air and water vapor permeability
- Clean peeling seals
- Low linting due to continuous filaments
- Low fiber tear
- Puncture resistance

These characteristics provide high value in terminally sterilized packaging of medical devices sterilized by a wide variety of methods. Several package configurations containing Tyvek® are used within the medical device industry. Packages such as chevron peel pouches and header bags are composed of Tyvek® sealed to flat, unshaped, flexible film in a wide variety of length and width dimensions. In addition, Tyvek® is commonly used in packages made with a Form/Fill/Seal (FFS) process and equipment using rigid or flexible forming films, as well as lidding material for preformed rigid trays.

Both adhesive coated and uncoated Tyvek® are used in medical packaging. When uncoated Tyvek® is used, the film web contains the adhesive layer to form the seal between the film and the Tyvek®.

A variety of converting steps may be required prior to using Tyvek® in medical packaging. Some will have the adhesive coated onto the Tyvek® prior to use, while most will be printed, slit or die cut before incorporation into the final package.

The permeability and chemical inertness of Tyvek® allow its use in a variety of sterilization processes. The sterile barrier systems using Tyvek® are commonly sterilized using ethylene oxide (EO) gas, gamma and electron-beam radiation. In addition, steam sterilization may be used if temperatures are controlled to avoid melting the Tyvek®. Tyvek® has been shown to meet packaging criteria for steam sterilization under controlled conditions (250°F to 260°F [121°C to 127°C] at 30 psi for 30 minutes). Emerging low-temperature sterilization methods such as: gas plasma with hydrogen peroxide, vapor phase hydrogen peroxide with peracetic acid, ozone and chlorine dioxide, require Tyvek® packaging because cellulosic porous materials are adversely affected by these strong oxidizing environments.

This document is used to demonstrate the compliance of Tyvek® with the ISO 11607-1:2006 standard. Tyvek® falls under sections 4 and 5. This document lists each clause from ISO 11607-1 that contains a requirement, followed by compliance information for the requirement. There are other DuPont documents that are referred to in this document and they are all available at www.MedicalPackaging.DuPont.com

4. GENERAL REQUIREMENTS

The numbers in the following sections refer to the specific clauses in ISO 11607-1.

4.2. Quality systems

4.2.1 The activities described within this part of ISO 11607-1:2006 *shall* be carried out within a formal quality system.

Tyvek® production facilities located in Richmond, VA, and Luxembourg are ISO 9001:2008 certified. As a requirement for certification, both facilities have a Quality Systems Manual. The Quality Systems Manual is an evergreen document and the controlled copy is kept on file. Our performance against it is the subject of semi-annual audits as part of retaining ISO 9001:2008 Registration, and is available to the auditors of our facilities. Changes to the manual may only be made with appropriate approvals. The current ISO 9001:2008 Registration Certificates are available at www.MedicalPackaging.DuPont.com

4.3 Sampling

The sampling plans used for selection and testing of packaging systems *shall* be appropriate to packaging systems being evaluated. Sampling plans *shall* be based upon statistically valid rationale.

Sampling and physical property testing for Tyvek® 1073B, Tyvek® Asuron™ (4070B), Tyvek® 1059B, Tyvek® 2FS™ (4058B) and Tyvek® 4057B are conducted per procedures associated with ISO 9001:2008 quality systems registration. Samples of Tyvek® are taken at the bonder windup, identified, and delivered to the in-area lab for physical property testing.

All routine physical property tests run on bonded Tyvek® are performed in the in-area lab. Testing is intended to satisfy Product Characterization, Process Control, and Measurement Control.

Samples are managed using the laboratory information management system (LIMS). Every sample is identified with a LIMS sample label. The sample label contains all necessary information needed to track a test result back to finished product.

Tyvek® is produced in full mill rolls that are approximately 10 feet wide and have a diameter of approximately three feet. These full mill rolls are then slit into multiple smaller packages according to the customer requirements. Full mill rolls are sampled uniformly across their width (typically 12 samples/full mill roll) to calculate roll averages. Thickness measurements are based on individual values (typically 112 samples/full mill roll) versus full mill roll averages. The average thickness is determined by pooling the ~112 data points from a roll with individual data points from other rolls and averaged. Test method variance related to equipment and analysis is included in the observed values. Other sampling plans and test methods may yield different values.

4.4 Test methods

4.4.1 All test methods used to show compliance with this International Standard shall be validated and documented.

All physical properties of Tyvek® that are used to demonstrate acceptable material for packaging terminally sterilized medical devices are measured by validated DuPont test methods that are comparable to recognized, national and international standards. DuPont conducts testing as shown in Table I.

Table I. Test methods used for measuring material properties

Property	Comparable Standard Test Methods		Deviations from Standard Test Methods
	Richmond, VA	Luxembourg	
Basis Weight	ASTM D3776	EN ISO 536	Modified sample size.
Delamination	ASTM D2724	ASTM D2724	Modified for speed and gauge length.
Gurley-Hill Porosity	TAPPI T460[1]	ISO 5636-5[2]	1. Modified sample size. 2. Modified for sealing fluid characteristics.
Opacity	TAPPI T425	ISO 2471	Modified for different backing standards, area and illumination.
Thickness (individual)	ASTM D1777[1]	EN ISO 534	1. 7.15 psi, 0.625-in. diameter presser foot.
Tensile and Elongation	ASTM D5035	EN ISO 1924-2	Modified for speed and gauge length.
Elmendorf Tear	ASTM D1424	EN 21974	—
Hydrostatic Head	AATCC TM 127	EN 20811	Rate of use: 60 cm H_2O/min.
Mullen Burst	ASTM D774	ISO 2758	—
Bendtsen Air Permeability	ISO 5636-3	ISO 5636-3	—
Spencer Puncture	ASTM D3420	ASTM D3420	Modified for 9/16-in. (14.28-mm) probe

4.4.2 Test method validation *shall* demonstrate the suitability of the method as used. The following elements *shall* be included:

- Establishment of a rationale for the selection of the appropriate tests for the packaging system
- Establishment of acceptance criteria; pass/fail is a type of acceptance criterion
- Determination of test method repeatability
- Determination of test method reproducibility
- Determination of test method sensitivity for integrity tests

Equipment calibration procedures for quality critical instruments and lab measurement control are conducted per internal procedures associated with ISO 9001:2008 quality systems registration.

The establishment of test methods was based on ISO 11607-1 Appendix B recommendations for test methodology. The accuracy and reliability of test results are highly dependent on the calibration of test equipment and the control of the testing environment, sampling process, and the testing process. The DuPont standard operating procedure specifies the calibration and control system for the in-area test lab equipment to ensure data is consistently accurate. The test data on routine production samples is used to certify product meets established standards and to control processing conditions that impact physical and chemical properties. All test equipment is calibrated on a specified frequency using gauges traceable to nationally recognized standards or locally developed standards.

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