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

## 4. General requirements

4.2 Quality systems

4.3 Sampling

4.4 Test methods

4.5 Documentation

## 5. Materials and preformed sterile barrier systems

5.1 General requirements

5.2 Microbial barrier properties

5.3 Compatibility with the sterilization process

5.4 Compatibility with the labeling system

5.5 Storage and transport

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 cellulose 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.

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Comparable Standard Test Methods</th>
<th>Deviations from Standard Test Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Richmond, VA</td>
<td>Luxembourg</td>
</tr>
<tr>
<td>Basis Weight</td>
<td>ASTM D3776</td>
<td>EN ISO 536</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Modified sample size.</td>
</tr>
<tr>
<td>Delamination</td>
<td>ASTM D2724</td>
<td>ASTM D2724</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Modified for speed and gauge length.</td>
</tr>
<tr>
<td>Gurley-Hill Porosity</td>
<td>TAPPI T460¹</td>
<td>ISO 5636-5²</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. Modified sample size.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Modified for sealing fluid</td>
</tr>
<tr>
<td></td>
<td></td>
<td>characteristics.</td>
</tr>
<tr>
<td>Opacity</td>
<td>TAPPI T425</td>
<td>ISO 2471</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Modified for different backing</td>
</tr>
<tr>
<td></td>
<td></td>
<td>standards, area and illumination.</td>
</tr>
<tr>
<td>Thickness (individual)</td>
<td>ASTM D1777¹</td>
<td>EN ISO 534</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. 7.15 psi, 0.625-in. diameter</td>
</tr>
<tr>
<td></td>
<td></td>
<td>presser foot.</td>
</tr>
<tr>
<td>Tensile and Elongation</td>
<td>ASTM D5035</td>
<td>EN ISO 1924-2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Modified for speed and gauge length.</td>
</tr>
<tr>
<td>Elmendorf Tear</td>
<td>ASTM D1424</td>
<td>EN 21974</td>
</tr>
<tr>
<td>Hydrostatic Head</td>
<td>AATCC TM 127</td>
<td>EN 20811</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rate of use: 60 cm H₂O/min.</td>
</tr>
<tr>
<td>Mullen Burst</td>
<td>ASTM D774</td>
<td>ISO 2758</td>
</tr>
<tr>
<td></td>
<td></td>
<td>—</td>
</tr>
<tr>
<td>Bendtsen Air Permeability</td>
<td>ISO 5636-3</td>
<td>ISO 5636-3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>—</td>
</tr>
<tr>
<td>Spencer Puncture</td>
<td>ASTM D3420</td>
<td>ASTM D3420</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Modified for 5/16-in. (14.28-mm)</td>
</tr>
</tbody>
</table>

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.
The Tyvek® in-area lab controls the measurement system by using a standard sample to monitor the repeatability and stability of most instruments in the lab. This provides a reliable method for detecting significant deviations in instrument readings due to instrument failure. Following is a summary of the standard control procedure:

- A standard sample roll is selected from routine production that represents a stable process condition in spinning and bonding.
- Several samples from this roll are tested to establish control limits.
- The standard sample is tested on a regular schedule on each instrument and the results are monitored.
- Corrective action is taken when a drift is detected.

4.4.3 Unless specified in test methods, test samples shall be conditioned at (23 ± 1)°C and (50 ± 1) % relative humidity for 24h.

All samples used for product release are tested in a controlled laboratory environment. Because Tyvek® is hydrophobic, samples are not stabilized for 24 hours prior to testing.

4.5 Documentation

4.5.1 Demonstration of compliance with the requirements of this standard shall be documented.

4.5.2 All documentation shall be retained for a specified period of time. The retention period shall consider factors such as regulatory requirements, expiry date and traceability of the medical device or sterile barrier system.

All documents that illustrate the compliance of Tyvek® with ISO 11607-1:2006 are retained for a specified period of time. This time period varies depending on the type of document and is specified in our quality procedures.

5. MATERIALS AND PREFORMED STERILE BARRIER SYSTEMS

Tyvek® has been used to package terminally sterilized medical devices in a variety of global climates since 1972. Because it is made of high-density polyethylene fibers, it is not affected by climatic changes in humidity, temperature, or atmospheric pressure. Because its melting point is 275°F (135°C), steam sterilization must be limited to <260°F (<127°C) temperature cycles. Exposure to UV light should be limited to less than one month. Normal shipping, handling and storage conditions should be used. Compatible ink offerings and labeling systems have been developed and most major manufacturers offer them to the market.

The administration of essential ingredients is conducted per standard operating procedures, specifying responsibility leading to the implementation of a system for the set-up, receipt and release of essential materials. Each shipment of polymer is received with a Certificate of Analysis demonstrating that the specification parameters are met.

5.1 General requirements

5.1.3 The conditions under which the material and/or preformed sterile barrier system are produced and handled shall be established, controlled and recorded, if applicable, in order to ensure that:

a) the conditions are compatible with the use for which the material and/or sterile barrier system is designed;

b) the performance characteristics of the material and/or sterile barrier system are maintained.

Tyvek® is a highly inert material and, once manufactured, it typically does not change unless directly exposed to UV light for more than 30 days.
5.1.4 As the minimum, the following shall be considered:

a) Temperature range

Toughness and flexibility are retained down to -100°F (-73°C). When exposed to heat, Tyvek® begins to shrink at approximately 270°F (132°C) and melts at 275°F (135°C). Under actual processing conditions, the temperature can influence the handling of the web and the range of exposures should be controlled or validated. It is suggested that the web temperature should not exceed 175°F (79°C).

b) Pressure range

The ability to perform over a range of pressures is a critical characteristic of Tyvek® when incorporated into a sterile barrier system (SBS). Porosity is the fabric characteristic related to pressure an SBS may experience and allows for the equilibration of pressure differentials across a sealed SBS. The extent of the porosity necessary for an SBS is an attribute only a medical device manufacturer can determine based on the sterilization processing, shipping, handling and storage the packaging system will be exposed to during its life cycle.

c) Humidity range

Tyvek® is hydrophobic and is not affected by moisture. Tyvek® maintains its strength regardless of humidity.

d) Maximum rate of change of the above, where necessary

As a packaging material, the rate of temperature, pressure and humidity changes are not applicable. These elements must be considered once Tyvek® becomes part of an SBS.

e) Exposure to sunlight or UV light

Physical properties of Tyvek® are degraded with extended exposure to direct sunlight (ultraviolet rays).

f) Cleanliness

Tyvek® is composed of essentially continuous fibers and does not generate a significant amount of lint particles under conditions of ordinary use.

g) Bioburden

The process of manufacturing Tyvek® allows only short periods of time when the sheet is subject to airborne particulates and microbes; therefore, the bioburden on the surface of the Tyvek® is very low. This low bioburden does not add significantly to the required sterilization time. The typical bioburden of all Tyvek® medical packaging styles is less than 100 colony forming units (cfu) per ft².

h) Electrostatic conductivity

In some processing steps, Tyvek® may generate static electricity unless treated with antistatic agents. Styles intended for medical packaging do not contain an antistatic agent. Untreated styles can build a static charge during roll or sheet handling and should not be handled in areas where there is the potential for explosive vapor/air mixtures.

5.1.5 The source, history and traceability of materials, especially recycled materials, shall be known and controlled to ensure that the finished product will consistently meet the requirements of this part of ISO 11607.

The source history and traceability of incoming and outgoing materials are controlled by our quality control procedures. Recycled materials are not used to manufacture Tyvek® medical packaging styles.

5.1.6 The following properties shall be evaluated:

a) Microbial barrier

The microbial barrier properties of Tyvek® are superior to medical-grade papers and are well documented in the DuPont Technical Reference Guide for Medical and Pharmaceutical Packaging (Section 3) located at http://www2.dupont.com/Medical_Packaging/en_US/tech_info/index.html
b) Biocompatibility and toxicological attributes

Biocompatibility and other toxicological attributes of Tyvek® medical packaging styles are acceptable and are documented 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

c) Physical and chemical properties

The physical properties of Tyvek® styles intended for medical packaging can be found in specifications and miscellaneous properties tables in the DuPont Technical Reference Guide for Medical and Pharmaceutical Packaging (Section 2) located at http://www2.dupont.com/Medical_Packaging/en_US/tech_info/index.html

These specifications and miscellaneous properties serve as a guide for medical device manufacturers to determine the level of protection required for a particular device.

Because Tyvek® is made of high-density polyethylene, it is relatively chemically inert. The chemical resistance of Tyvek® to various chemicals is available at http://www2.dupont.com/Tyvek/en_US/assets/downloads/tyvek_handbook.pdf

d) Compatibility with respect to forming and sealing processes

Tyvek® has been used as a packaging material for medical devices since 1972. It is customary for the user of a sterile barrier system (SBS) to specify the strength requirements required for its use. It is intended that the package or SBS strength selected will be sufficiently strong so as to assure SBS integrity through the user’s distribution, handling and storage systems. The strength of a preformed SBS seal should be determined by the manufacturer of that system.


e) Compatibility with respect to the intended sterilization process(es)

Tyvek® medical packaging styles are compatible with all approved sterilization methods, including: ethylene oxide, electron-beam, gamma irradiation, steam (under controlled conditions), and low-temperature oxidative sterilization processes. The effects of sterilization on Tyvek® medical packaging styles are documented in the DuPont Technical Reference Guide for Medical and Pharmaceutical Packaging (Section 4) located at http://www2.dupont.com/Medical_Packaging/en_US/tech_info/index.html

f) Any shelf-life limitations for pre-sterilization and post-sterilization storage

Tyvek® medical packaging styles should be stored under the same conditions as one would store a medical device. Tyvek® should not be exposed to direct sunlight for more than 30 days.

Tyvek® is capable of maintaining package integrity and sterility for at least five years. The effects of post-sterilization storage are documented in the DuPont Technical Reference Guide for Medical and Pharmaceutical Packaging (Section 5) located at http://www2.dupont.com/Medical_Packaging/en_US/tech_info/index.html

5.1.7 Materials, e.g. wrapping materials, paper, plastic film, nonwovens, reusable fabrics, shall meet the following general performance requirements:

a) Materials shall be non-leaching and odorless under specified conditions of use to such an extent that neither performance nor safety is impaired and the medical devices with which they are in contact are not adversely affected.

Tyvek® is an article made of high density polyethylene (HDPE) and is odorless. Elemental analysis of selected Tyvek® styles shows various elements including heavy metals are in the range of trace amount or are non-detectable. Tyvek® medical packaging styles meet the extractable or composition requirements of various regulations such as 21CFR 177.1520, Commission Regulation (EU) N° 10/2011 and European Pharmacopoeia, Section 3.1.5.
b) Materials shall be free of holes, cracks, tears, creases, or localized thickening and/or thinning sufficient to impair functioning.

Standard operating procedures (SOPs) are used within the manufacturing facilities to identify and correct visual anomalies. A summary of the SOPs describing the types of anomalies seen in Tyvek® and the release standards for Tyvek® medical packaging styles are listed below. Corrective actions when an anomaly is detected are also defined.

• Inspecting, grading, segregating and dispositioning of product

SOPs define the roles and responsibilities required to deliver the best product possible to our customers, including: guidelines for inspecting, grading, segregating and dispositioning Tyvek®; specifications for moving sheet and stationary sheet; inspections tables describing anomalies, their causes, detection methods; and instructions related to segregating and dispositioning product when anomalies are detected.

• Anomaly descriptions and possible causes

SOPs are designed to give a detailed description and definition of each known anomaly, the frequency of occurrence, and detection process. There are two categories of anomalies:

  Minor:
  An anomaly that does not affect performance but should be eliminated. This anomaly will be recorded and action taken to correct and prevent the anomaly. This type of anomaly will ship to customers.

  Major:
  An anomaly that does affect performance and must not ship. This anomaly will be recorded and action taken to correct and prevent the anomaly. This type of anomaly will not ship to customers.

• Tracing and clearing of anomalies

Once a major anomaly is detected, the anomaly must be traced and cleared per SOPs. This prevents unacceptable material from shipping to customers.

c) Materials shall have a basis weight (mass per unit area) which is consistent with the specified value.

See the specification properties tables in the DuPont Technical Reference Guide for Medical and Pharmaceutical Packaging (Section 2) which is available at http://www2.dupont.com/Medical_Packaging/en_US/tech_info/index.html

d) Materials shall exhibit acceptable levels of cleanliness, particulate matter and linting.

Internal processes specify release limits for cleanliness and particulate matter. Tyvek® does not generate a significant amount of lint particles under conditions of ordinary use. Refer to the DuPont Technical Reference Guide for Medical and Pharmaceutical Packaging (Section 3), which is available at http://www2.dupont.com/Medical_Packaging/en_US/tech_info/index.html

e) Material shall comply with established specific or minimum physical properties such as tensile strength, thickness variation, tear resistance, air permeance and burst strength.

For Tyvek® medical packaging styles, the established specification properties are Gurley Hill, Delamination and Basis Weight. The specific values for these can be found in the DuPont Technical Reference Guide for Medical and Pharmaceutical Packaging (Section 2), which is available at http://www2.dupont.com/Medical_Packaging/en_US/tech_info/index.html

Additional properties that are important when considering alternative materials for your specific applications can also be found in the DuPont Technical Reference Guide for Medical and Pharmaceutical Packaging (Section 2).

f) Materials shall comply with established specific chemical characteristics (such as pH value, chloride, and sulfate contents) to meet the requirements of the medical device, packaging system or sterilization process.

Tyvek® is an article made of high density polyethylene (HDPE) and is odorless. Elemental analysis of selected Tyvek® styles shows various elements including heavy metals are in the range of trace amount or are non-detectable. Tyvek® medical packaging styles meet the extractable or composition requirements of various regulations such as 21CFR 177.1520, Commission Regulation (EU) N° 10/2011 and European Pharmacopoeia, Section 3.1.5.
g) Materials shall not contain or release material known to be toxic in sufficient quantity to cause a health hazard either before, during or after sterilization under the conditions of use.

The toxicological attributes of Tyvek® medical packaging styles are documented in the DuPont Technical Reference Guide for Medical and Pharmaceutical Packaging (Section 4) located at http://www2.dupont.com/Medical_Packaging/en_US/tech_info/index.html

5.1.8 In addition to the requirements given in 5.1.1 through 5.1.6, adhesive-coated materials shall meet the requirements listed below.

Adhesive coated Tyvek® is sold by sterile packaging manufacturers and each will require a different set of process conditions to give the required package strength and integrity. The medical device manufacturer must validate the processes used for the coated product they are using.

5.1.10 In addition to the requirements given in 5.1.1 through 5.1.7, reusable containers shall meet the requirements given below.

Tyvek® is not designed to produce reusable containers.

5.2 Microbial barrier properties

5.2.1 The impermeability of a material shall be determined in accordance with Annex C.

Tyvek® is not considered to be an impermeable material.

5.2.2 Demonstrating that the material is impermeable shall satisfy the microbial barrier requirements.

Tyvek® is not considered to be an impermeable material.

5.2.3 Porous materials shall provide an adequate microbial barrier to microorganism in order to provide integrity of the sterile barrier and product safety.

The microbial barrier properties of Tyvek® are superior to medical-grade papers and are well documented 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

5.3 Compatibility with the sterilization process

5.3.1 It shall be demonstrated that the materials and preformed sterile barrier system are suitable for use in the specified sterilization process(es) and cycle parameters.

5.3.2 The performance of the materials shall be evaluated to ensure that the material performance remains within specified limits after exposure to all the specified sterilization processes.

Tyvek® medical packaging styles are compatible with all approved sterilization methods, including: ethylene oxide, electron-beam, gamma irradiation, steam (under controlled conditions), and low-temperature oxidative sterilization processes. The effects of sterilization on medical packaging styles are documented 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
5.4 Compatibility with the labeling system

The labeling system **shall:**

a) remain intact and legible until the point of use;

Ink manufacturers have developed specific inks to print on medical packaging styles of Tyvek®. To achieve consistent, high-quality print, the appropriate ink must be used.

b) be compatible with the materials, sterile barrier system and medical device during and after the specified sterilization process(es) and cycle parameters and **shall not** adversely affect the sterilization process;

c) not be printed or written in ink of a type which can be transferred to the medical device nor react with the packaging material and/or system to impair the utility of the packaging material and/or system nor change colour to an extent which renders the label illegible.

The labeling of products made by the Tyvek® manufacturing plants is aimed at meeting the needs of our customers and contractors. It must further account for and trace product through all manufacturing steps. Labels are applied to rolls of Tyvek® during the inspection and packaging operations. These labels provide sufficient information to identify the product and to trace product processing at the manufacturing site using the package number (bar-coded) as the primary identifier.

Because the label is removed prior to final processing; the reaction of the ink and label material is not applicable.

5.5 Storage and transport

5.5.1 Materials and preformed sterile barrier systems **shall** be packaged to provide the protection necessary to maintain the performance characteristics during transport and storage.

The material wrapping system used by DuPont is designed to provide the necessary protection to the rolls through the global supply chain. This would include transport by rail, truck, ocean containers and air. The rolls are wrapped with a polyethylene stretch film in either an axial or barrel method.

These methods of wrapping protect the Tyvek® rolls from contamination and damage during distribution and handling. There are no restrictions on transport and storage of Tyvek® other than avoiding direct exposure to UV light for more than 30 days.

5.5.2 Materials and preformed sterile barrier systems **shall** be transported and stored under conditions that ensure that the performance characteristics remain within specified limits.

This can be accomplished by:

a) demonstrating retention of these characteristics under defined storage conditions;

b) ensuring that storage conditions remain within specified limits.

There are no restrictions on transport and storage of Tyvek® other than avoiding direct exposure to UV light for more than 30 days.
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You can also find links to other resources in your country and information in other languages at this website.