

# Packaging System Services for Medical Devices

**W**uXi AppTec provides medical device manufacturers with design, development, testing, and process validation services for their packaging systems. Testing services can be used to demonstrate compliance with the requirements cited in ANSI/AAMI ISO 11607, Packaging for Terminally Sterilized Medical Devices Part 1 and Part 2. Additional services include packaging system performance testing and Sterile Barrier System (SBS) stability testing.

WuXi AppTec is a global leader in providing discovery, testing and manufacturing services for the pharmaceutical, biotechnology and medical device industries. Research-driven and customer-focused, with operations in China and the U.S., WuXi AppTec offers a broad and integrated portfolio of services designed to assist our customers with cost-effective and efficient outsourcing solutions.

**WX**  
**LISTED**  
**NYSE**

See reverse side for a more detailed listing of available testing services.

## Packaging System Design/Development and Testing Services

- Packaging system materials selection, design and development
- Packaging system design qualification protocols and test plans
- Packaging system design qualification testing or “stressing,” including shock, vibration, compression, and distribution simulation

## Sterile Barrier System (SBS) Design/Development and Testing Services

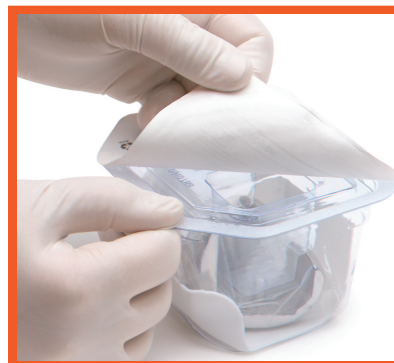
- SBS design
- SBS stability protocols and test plans
- SBS materials selection testing, including cytotoxicity/biocompatibility and sterilization compatibility
- SBS integrity, whole package and seal strength testing, including:
  - Accelerated and real-time aging
  - SBS materials strength stability testing
  - SBS seal integrity evaluation
  - SBS seal strength stability evaluation

## Process Validation

- Packaging system design qualification protocols and test plans (packaging performance testing)
- Critical manufacturing process / sealing process validations (IQ/OQ/PQ)

## Additional Services

- ISO 11607 compliance reviews and audits
- Troubleshooting and problem resolution consulting
- FDA package-related inspection deficiencies (483) reviews and corrective action



For more information on WuXi AppTec's services please contact:

**U.S.**  
+1 (651) 675 2000 • +1 (888) 794 0077  
info@wuxiapptec.com

WE ARE DETERMINED TO SERVE YOU BETTER<sup>®</sup>

[www.wuxiapptec.com](http://www.wuxiapptec.com)

# Packaging System Testing Services for Medical Devices

## Sterile Barrier System (SBS) Testing

### SBS Seal and Whole Package Strength Testing

- ASTM F88 *Standard Test Method for Seal Strength of Flexible Barrier Materials*
- ASTM F1140 *Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages for Medical Applications*
- ASTM F2054 *Standard Test Method for Burst Testing of Flexible Package Seals Using Internal Air Pressurization within Restraining Plates*

### SBS Integrity Testing

- ASTM D3078 *Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission*
- ASTM F1886 *Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection*
- ASTM F1929 *Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration*
- ASTM F2096 *Standard Test Method for Detecting Gross Leaks in Porous Medical Packaging by Internal Pressurization (Bubble Test)*

### SBS Materials Testing

- ASTM D256 *Standard Test Methods for Determining the Izod Pendulum Impact Resistance of Plastics*
- ASTM D726 *Standard Test Method for Resistance of Nonporous Paper to Passage of Air (Gurley Porosity Test)*
- TAPPI T-460 *Air resistance of paper (TAPPI Gurley Test Method)*
- ASTM D882 *Test Method of Tensile Properties of Thin Plastic Sheeting*
- ASTM D1709 *Test Method for Impact Resistance of Plastic Film by Free-Falling Dart Method*
- ASTM D1922 *Standard Test Method for Propagation Tear Resistance of Plastic Film and Thin Sheeting by Pendulum Method (Elmendorf Tear)*
- ASTM D1938 *Standard Test Method for Tear-Propagation Resistance (trouser tear) of Plastic Film and Thin Sheeting by a Single-Tear Method*
- ASTM D3420 *Standard Test Method for Dynamic Ball Burst Pendulum Impact Resistance of Plastic Film (Spencer Puncture)*
- ASTM F392 *Standard Test Method for Flex Durability of Flexible Barrier Materials (Gelbo Test)*
- ASTM F1306 *Standard Test Method for Slow Rate Penetration Resistance of Flexible Barrier Films and Laminates*
- ASTM F2217 *Standard Practice for Coating / Adhesive Weight Determination*
- ASTM F2251 *Standard Test Method for Thickness Measurement of Flexible Packaging Materials*
- ASTM F2475 *Standard Guide for Biocompatibility Evaluation of Medical Device Packaging Materials*

### SBS Stability Testing

- ASTM F1980-07 *Standard Guide for Accelerated Aging of Sterile Medical Device Packages*
- Real-Time Aging Sample Storage and follow up

## Packaging System Design Qualification Testing

- ASTM D4169 *Standard Practice for Performance Testing of Shipping Containers and Systems*
- ASTM D7386 *Standard Practice for Performance Testing of Packages for Single Parcel Delivery Systems*
- ISTA Pretest shipment test procedures Series 3A
- ISTA Pretest shipment test procedures Series 4AB
- If requested, ISTA 1 and 2 Series



WuXi AppTec's testing services are designed to meet the requirements of regulatory agencies worldwide. For more information, please contact a WuXi AppTec Account Manager at (+1) 651-675-2000 or 888-794-0077 or visit [www.wuxiapptec.com](http://www.wuxiapptec.com)