



### Recognized Consensus Standards

**Recognition List Number:** 014 **Effective Date:** 03/31/2006

#### **Part B: SUPPLEMENTARY INFORMATION**

**Item 168: ASTM F2338-05, Standard Test Method for Nondestructive Detection of Leaks in Packages by Vacuum Decay Method. (Sterility)**

**Date of Standard:** 2005.

**Address of Standards Organization:**

ASTM INTERNATIONAL (ASTM)  
100 BARR HARBOR DRIVE  
WEST CONSHOHOCKEN, PA 19428-2959

**CDRH Office and Division Associated with Recognized Standards:**

ALL OFFICES AND DIVISIONS IN CDRH

**Devices Affected:**

Any devices that are sterilized and packaged. Packages that can be nondestructively evaluated by this test method include: Rigid and semi-rigid non-lidded trays; trays or cups sealed with porous barrier lidding materials; rigid, nonporous packages; flexible, nonporous packages. This test method is capable of detecting package leaks using an absolute or differential pressure transducer leak detector.

**Processes Affected:**

510(k), IDE, PMA, PDP, HDE, Design Control Input, Quality System Regulation

**Type of Standard:**

Horizontal

**Extent of Recognition:**

Complete standard and any annexes

**Relevant Guidance:**

To be used in conjunction with AAMI/ANSI/ISO 11607:2000, Packaging for terminally sterilized medical devices, 2 ed and AAMI TIR 22:1998; TIR 22/A1:2001

**FDA Technical Contact:**

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Reference:

[http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/Detail.CFM?STANDARD\\_IDENTIFICATION\\_NO=15750](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/Detail.CFM?STANDARD_IDENTIFICATION_NO=15750)