

## EC DECLARATION OF CONFORMITY

**Date:** 03/01/09

**Name and address of manufacturer:**

Angela Kilgore, Quality Assurance Manager  
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United States of America

**Name and address of authorized representative:**

Kevin Waldron, Quality Assurance Manager  
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A Subsidiary of Thermo Fisher Scientific  
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United Kingdom

**Product designation:** Flash freeze tissue specimens

**Product number:**

Title	Catalog #	Configuration
Envi-Ro-Tech™ Freezer Spray	6769038	6 x 236ml

**ISO 14971:2000 (E):** Medical devices – Application of risk management to medical devices

**Directive 98/79/EC** of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

**Directive 1999/45/EC** of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations, and administrative provisions of the Member States relating to the classification, packaging, and labeling of dangerous preparations.

**ISO 13485:2003:** Medical Devices—Quality management systems—Requirements for regulatory purposes, and are registered by BSI Management Systems, certificate no. FM 522944.

**EN 980:2003:** Graphical symbols for use in the labeling of medical devices

**Approvals:**



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Angela Kilgore  
Quality Assurance Manager  
Richard-Allan Scientific a subsidiary of  
Thermo Fisher Scientific