ThermoFisher SCIENTIFIC

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EC DECLARATION OF CONFORMITY

Date: 7/23/09

Name and address of manufacturer:

Angela Kilgore, Quality Assurance Manager
Richard-Allan Scientific
A subsidiary of Thermo Fisher Scientific
4481 Campus Drive
Kalamazoo, Michigan 49008
United States of America

Name and address of authorized representative:

Kevin Waldron, Quality Assurance Manager
Thermo Shandon Ltd
A Subsidiary of Thermo Fisher Scientific
93-96 Chadwich Road, Astmoor, Runcorn, Cheshire WA7 1PR
United Kingdom

Product designation: Used as a cytoplasmic stain

Product number:

Title	Catalog #	Configuration
Eosin-Y Alcoholic	6766008 6766007	1 x 4L 2 x 1L
Eosin-Y Aqueous	6766010 6766009	1 x 4L 2 x 1L
Instant Eosin-Y Alcoholic	6765040	6/pk
Instant Eosin-Y Aqueous	6765540	6/pk
Eosin-Y Alcoholic	6766008 6766007	1 x 4L 2 x 1L
Eosin-Y Aqueous	6766010 6766009	1 x 4L 2 x 1L
Instant Eosin-Y Alcoholic	6765040	6/pk

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 27October 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:

Angela M. Kilgore

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