

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 nuclear stain

Product number:

Title	Catalog #	Configuration
Harris Hematoxylin Acidified	6765004	1 x 4L
	6765003	2 x 1L
Harris Hematoxylin Non-Acidified	6765002	1 x 4L
	6765001	2 x 1L
Gill 1 Hematoxylin	6765006	1 x 4L
	6765005	2 x 1L
Gill 2 Hematoxylin	6765008	1 x 4L
	6765007	2 x 1L
Gill 3 Hematoxylin	6765010	1 x 4L
	6765009	2 x 1L
Instant Hematoxylin	6765015	6/pack – 6L

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:



Angela Kilgore
Quality Assurance Manager
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Thermo Fisher Scientific