

EC DECLARATION OF CONFORMITY

Date: 2010-12-02

Name and address of manufacturer:

Angela Kilgore, Quality Assurance / Regulatory Affairs 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 Limited
Subsidiary of Thermo Fisher Scientific
Tudor Road, Manor Park,
Runcorn, Cheshire WA7 1TA
United Kingdom

Product designation: Used for infiltration and embedding of tissue specimens

Product number:

Title	Catalog #	Configuration
Paraffin, Type 1	8334	10 x 2 lb bags
Paraffin, Type 3	8335	10 x 2 lb bags
Paraffin, Type 6	8336	10 x 2 lb bags
Paraffin, Type 9	8337	10 x 2 lb bags
Paraffin, Type H	8338	10 x 2 lb bags
Paraffin, Type L	8339	10 x 2 lb bags
Shandon Precision Cut Paraffin	B1002490	4 x 2.5 kg bags
Fast Flex Paraffin	9810	10 x 2 lb bags
Histoplast Paraffin	6774006	1 x 2.5 kg bag
Histoplast Paraffin	6774060	4 x 2.5 kg bag
HistoPlast PE	8330	8 x 1 kg bags
HistoPlast PE	8330S	sample
HistoPlast IM	8331	8 x 1 kg bags
HistoPlast LP	8332	8 x 1 kg bags
Paraplast	501006	8 x 1 kg bags
Paraplast+	501004	8 x 1 kg bags
Paraplast X-tra	501002	8 x 1 kg bags

ISO 14971:2009: 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 980:2008: Graphical symbols for use in the labeling of medical devices

IVDD Classification: Class I
Compliance Annex: Directive 98/79/EC, Annex III

Approvals:



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