

	Declaration of Conformity	Doc #: TF-05DOC Revision: A Date: 1/18/2022
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EU DECLARATION OF CONFORMITY

We, Leica Biosystems Richmond Inc, 5205 Route 12, Richmond, IL 60071, declare under our sole responsibility that the product(s) to which this declaration relates is in conformity with the following standard(s) or other normative documents(s) and proves the conformity of the designated product with the provisions of the European In Vitro Diagnostic Regulation.

Products covered in this DoC conform to: Regulation (EU) 2017/746 of the European Parliament and of the Council on 5 April 2014 on *in vitro* diagnostic medical devices.

Contact Information

Legal Leica Biosystems Richmond Inc
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Product Identification

Product Grouping Frozen Section Compound (*see Appendix 1 for the complete list of*
Name: *products*)

Basic UDI-DI: 849832005UP

Intended Use: The Leica Biosystems Frozen Section Compounds may be used in the
 process of cryo-sectioning to facilitate the production of frozen
 sections. The compound bonds and encapsulates tissue specimens
 to the object holder for cryo-sectioning. The embedded tissue is
 then processed for serial sectioning, staining and ultimately a
 diagnosis is made by qualified personnel.

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Notified Body

Contact Info:	BSI Group America Inc 12950 Worldgate Drive, Suite 800 Herndon, VA 20170-6007 United States
CE Certificate No:	NA, Class A Products

Common Specifications: See Appendix 2 for a list of common specifications (CS) applicable to the product group address in this DoC.

Date of First CE mark: 02/2013

Mica Lewis

Electronically signed by: Mica Lewis
Reason: This electronic signature serves as my approval of this document
Date: Jan 19, 2022 07:54 CST

19-Jan-2022

Name: Mica Lewis

Function: Person Responsible for Regulatory Compliance for Leica Biosystems Richmond Inc

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Appendix 1 Product list

Product Name	Product Number	Risk Class /	UDI-DI
FSC 22 Frozen Section Compound Clear	3801480	Class A / Rule 5	00849832001317
FSC 22 Frozen Section Compound Blue	3801481	Class A / Rule 5	00849832012443
Cryo-Gel	39475237	Class A / Rule 5	00849832012429
Tissue Freezing Medium	14020108926	Class A / Rule 5	00849832012214

**See risk classification and rule in In Vitro Diagnostic Regulation 2017/746, annex VIII*

Appendix 2 Common Specifications

Number and Standard	Description of standard	Year
NA	NA	NA






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Final Audit Report

2022-01-19

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