

	<b>Declaration of Conformity</b>	<b>Doc #:</b> TF-01DOC <b>Revision:</b> A <b>Date:</b> 11/22/2021
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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 Manufacturer:** Leica Biosystems Richmond Inc  
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The Netherlands  
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### Product Identification

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

**Basic UDI-DI:** 849832001UF

**Intended Use:** The Leica Biosystems Paraffins do not detect or measure an analyte or marker. These products are used for the process of infiltration and/or embedding of adequately fixed and appropriately processed tissue specimens prior to microtomy.

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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:** 09/2009

*Mica Lewis*

Electronically signed by:  
Mica Lewis  
Reason: This electronic  
signature serves as my  
approval of this document  
Date: Nov 22, 2021 08:29  
CST

22-Nov-2021

**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 / Rule*	UDI-DI
Emedding Media EM-400	3801320	Class A / Rule 5	00849832012566
Infiltration Medium	3801340	Class A / Rule 5	00849832012542
Blue Ribbon	3801360	Class A / Rule 5	00849832012573
Blue Ribbon	3801365	Class A / Rule 5	00849832018377
Formula "R"	3801450	Class A / Rule 5	00849832012528
Formula "R"	3801470	Class A / Rule 5	00849832012535
McCormick Paraplast	39501006	Class A / Rule 5	00849832013631
Leica Paraplast	39601006	Class A / Rule 5	00849832000969
McCormick Paraplast	39502012	Class A / Rule 5	00849832013655
Leica Paraplast	39602012	Class A / Rule 5	00849832013693
Leica Paraplast	3962012TR	Class A / Rule 5	00849832019282
McCormick Paraplast X-tra	39503002	Class A / Rule 5	00849832018384
Leica Paraplast X-tra	39603002	Class A / Rule 5	00849832013709
McCormick Paraplast Plus	39502004	Class A / Rule 5	00849832013648
Leica Paraplast Plus	39602004	Class A / Rule 5	00849832013686
Leica Paraplast High Melt	39601095	Class A / Rule 5	00849832013679
Leica Paraplast High Melt	39601098	Class A / Rule 5	00849832018407
Peloris Parablock	39V1001	Class A / Rule 5	00849832000976
Peloris Parablock X-tra	39V3001	Class A / Rule 5	00849832018414
HISTO-WAX	3808605E	Class A / Rule 5	00849832013129

*\*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









# IVDR TF-01 Wax DOC - 11.22.2021

Final Audit Report

2021-11-22

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