

	<h2 style="text-align: center;">Declaration of Conformity</h2>	<b>Doc #:</b> TF-29DOC <b>Revision:</b> A <b>Date:</b> 11/15/2021
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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

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### Product Identification

**Product Grouping Name:** SPECTRA (*see Appendix 1 for the complete list of products*)  
**Basic UDI-DI:** 849832029V5  
**Intended Use:** The SPECTRA H&E Staining Systems are intended to stain paraffin embedded, slide mounted tissue specimens for subsequent microscopic evaluation. The SPECTRA Mounting Media and Cover Glass are intended to provide a protection to slide mounted tissue specimens for subsequent microscopic evaluation and long term archival.

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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:** 08/2017



**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
HistoCore SPECTRA H&E Staining System S1	3801654	Class A / Rule 5	00849832013464
HistoCore SPECTRA H&E Staining System S2	3801655	Class A / Rule 5	00849832013471
HistoCore SPECTRA H&E Staining System S1-800	3801656	Class A / Rule 5	00849832013518
HistoCore SPECTRA H&E Staining System S2-800	3801657	Class A / Rule 5	00849832013525
HistoCore SPECTRA CV X1 Mounting Media	3801733	Class A / Rule 5	00849832015581
HistoCore SPECTRA CV Cover Glass	3800152	Class A / Rule 5	00849832013457

*\*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