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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
Manufacturer: 5205 Route 12
Richmond, IL 60071
SRN: US-MF-000014614
Phone: +1(815)678-2000
PRRC: Mica Lewis
E-mail: mica.lewis@leicabiosystems.com
Phone: +1(815)678-2000 ext 6110

Authorized EU Rep: CEpartner4U
Esdoornlaan 13, 3951 DB Maarn
The Netherlands
SRN: NL-AR-000000111

Product Identification

Product Grouping: Cytology Stains (*see Appendix 1 for the complete list of products*)
Name:
Basic UDI-DI: 849832015US
Intended Use: The Leica Biosystems Cytology Stains do not detect or measure an analyte or marker. The Leica Biosystems Cytology Stains are used to produce various colorations of the cytoplasm within the cellular elements of cytology specimens.

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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 18, 2022 14:44 CST

18-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
EA-50	3801620BBE	Class A / Rule 5	00849832001652
EA-50	3801620E	Class A / Rule 5	00849832001669
EA-50	3801621E	Class A / Rule 5	00849832001676
EA-50	3801622E	Class A / Rule 5	00849832001683
EA-65	3801640BBE	Class A / Rule 5	00849832012979
EA-65	3801640E	Class A / Rule 5	00849832012986
EA-65	3801641E	Class A / Rule 5	00849832001690
EA-65	3801642E	Class A / Rule 5	00849832001706
Papanicolaou Stain OG-6	3801660BBE	Class A / Rule 5	00849832001713
Papanicolaou Stain OG-6	3801660E	Class A / Rule 5	00849832001720
Papanicolaou Stain OG-6	3801661E	Class A / Rule 5	00849832001737
Orange G-6	3801662	Class A / Rule 5	00849832019329
Papanicolaou Stain OG-6	3801662E	Class A / Rule 5	00849832001744
EA-50 Modified	3801680	Class A / Rule 5	00849832019336
EA-50 Modified	3801680E	Class A / Rule 5	00849832012948
EA-50 Modified	3801682	Class A / Rule 5	00849832017912
EA-50 Modified	3801682E	Class A / Rule 5	00849832012962
Orange G	3803810	Class A / Rule 5	00849832013105

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

Appendix 2 Common Specifications

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Number and Standard	Description of standard	Year
NA	NA	NA

IVDR TF-15 Cytology Stains DOC - Rev A

Final Audit Report

2022-01-18

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