

	Declaration of Conformity	Doc #: TF-8DOC Revision: B Date: 5/25/2022
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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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The Netherlands
SRN: NL-AR-000000111

Product Identification

Product Grouping Hematoxylin (*see Appendix 1 for the complete list of products*)
Name:
Basic UDI-DI: 849832008UV
Intended Use: Leica Biosystems Richmond, Inc Hematoxylin stain solutions are ready to use stain solutions used for microscopic examination of a tissue section specimen or cell preparation. Hematoxylin stains the nuclei of the cells.

Notified Body

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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

Heloiza Chirnev

Electronically signed by:
Heloiza Chirnev
Reason: This electronic
signature serves as my
approval of this document
Date: May 25, 2022 10:39
CDT

Name: Heloiza Chirnev

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
Haematoxylin Gill I	3801500BBE	Class A / Rule 5	00849832012597
Haematoxylin Gill I	3801500E	Class A / Rule 5	00849832012603
Haematoxylin Gill I	3801501	Class A / Rule 5	00849832018025
Haematoxylin Gill I	3801501E	Class A / Rule 5	00849832012610
Haematoxylin Gill I	3801502	Class A / Rule 5	00849832018032
Haematoxylin Gill I	3801502E	Class A / Rule 5	00849832012627
Haematoxylin Gill II	3801520	Class A / Rule 5	00849832018049
Haematoxylin Gill II	3801520E	Class A / Rule 5	00849832012641
Haematoxylin Gill II	3801520BBE	Class A / Rule 5	00849832012634
Haematoxylin Gill II	3801521	Class A / Rule 5	00849832018056
Haematoxylin Gill II	3801521E	Class A / Rule 5	00849832018056
Haematoxylin Gill II	3801522	Class A / Rule 5	00849832018063
Haematoxylin Gill II	3801522E	Class A / Rule 5	00849832001546
Haematoxylin Gill III	3801540BBE	Class A / Rule 5	00849832012672
Haematoxylin Gill III	3801540E	Class A / Rule 5	00849832018070
Haematoxylin Gill III	3801541E	Class A / Rule 5	00849832012689
Haematoxylin Gill III	3801542E	Class A / Rule 5	00849832001553
Harris Hematoxylin	3801560	Class A / Rule 5	00849832002611
Harris Haematoxylin	3801560BBE	Class A / Rule 5	00849832001560
Harris Haematoxylin	3801560E	Class A / Rule 5	00849832001577
Harris Haematoxylin	3801561E	Class A / Rule 5	00849832001584

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Harris Hematoxylin	3801562	Class A / Rule 5	00849832002628
Harris Haematoxylin	3801562E	Class A / Rule 5	00849832001591
Hematoxylin 560	3801570	Class A / Rule 5	00849832018087
Hematoxylin 560	3801571	Class A / Rule 5	00849832018094
Hematoxylin 560MX	3801575	Class A / Rule 5	00849832015765
Hematoxylin	3803815	Class A / Rule 5	00849832013112

**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-08 Hematoxylin DOC - Rev B - FINAL

Final Audit Report

2022-05-25

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