

Declaration of Conformity in accordance with Regulation (EU) 2017/746 on In Vitro Diagnostic Medical devices: Class A BOND Ancillaries

Doc No: LBN-DoC-0007

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Manufacturer and / or Authorised Representative details.

Manufacturer:

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Single Registration Number (SRN): GB-MF-

000020595

Authorised Representative:

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Single Registration Number (SRN): NL-AR-

000000111

2 Manufacturer Responsibility Statement.

This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer, detailed in Section 1 of this declaration.

3 Basic UDI-DI.

Refer to Appendix 1.

4 Product name and catalogue code.

BOND Ancillaries. For product details refer to Appendix 1.

5 Risk Classification in accordance with Annex VIII.

The devices covered by this declaration, listed in Appendix 1, have been assigned the risk classification of A in accordance with Rule 5(a) of Annex VIII:

"Rule 5: The following devices are classified as class A: (a) products for general laboratory use, accessories which possess no critical characteristics, buffer solutions, washing solutions, and general culture media and histological stains, intended by the manufacturer to make them suitable for in vitro diagnostic procedures relating to a specific examination;"

For classifications details of individual products, refer to Appendix 1.

6 Conformity Statement.

The devices covered by this declaration, listed in Appendix 1, are in conformity with the relevant provisions of Regulation (EU) 2017/746 and are CE marked in accordance with Annex V.

7 Common Specifications.

There are currently no common specifications applicable for our devices. There are currently no standards harmonised with IVDR which LBN can utilise to demonstrate conformity. LBN prefer the use of harmonised standards to demonstrate conformity to the current essential requirements checklist per IVDD. LBN shall ensure the IVDs will conform to the IVDR and propose the solution for conformity as:

- 1) Using state of the art versions of standards which are harmonised under the current IVDD. This approach will not allow LBN to state conformity by using these standards alone, but it allows demonstration of part conformity to the IVDR.
- 2) Other published standards identified as candidates for harmonisation under the respective regulation, and
- 3) Utilise appropriate International and European consensus standards given that harmonised standards mostly originated from them.

For applicable standards refer to Appendix 2



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8	Notified Body, C	Conformity Assessme	nt Procedure & Certificate Details.	
	Name of notified	<u>-</u>	In accordance with Annex VIII, Rule 5(a) of the IVDR the	
		•	devices listed in Appendix 1 have been assigned the risk	
	Identification number of notified body:		classification of A. Conformity assessment by a notified	
			body is therefore not applicable.	
	Cfit		Colf Deployation of Confermation bearing an Association	
	Conformity assess	sment procedure:	Self Declaration of Conformity based on Annex II: Technical Documentation and Annex III: Technical	
			Documentation on Post-Market Surveillance.	
-	Certificates issued	l:	N/A	
9	Additional infor		1970	
	N/A			
	•			
10	Issuing and Sign	ing of Declaration.		
		of the manufacturer by	<i>r</i> :	
	Signature:			
		DocuSigned by:		
		Laura Tracy		
		Signer Name: Laura		
		Signing Reason: I app Signing Time: 31 Mar	prove this document ch 2022 7:28:31 AM PDT	
		(1B5DDD387086C4006	
	Name:	Laura Tracy		
	Position:	Director, Global Regulatory Affairs - Advanced Staining		
	Data of :			
	Date of issue:	31 March 2022		
	Place of issue:	Leica Biosystems New	/castle Ltd	



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Appendix 1 Device Details

Product (Catalogue) Code & Pack Size	SAP Code	IFU Product Name	Risk Classification Rule	Basic UDI-DI		
	AR0222	BOND Ready-to-Use Anti- Fluorescein Antibody 15 mL	Rule 5(a)	50553313ISHAFL00006RK		
AR0222, 15mL	Intended Purpose:	For <i>in vitro</i> diagnostic use. Anti-Fluorescein Antibody is intended for use with fluorescein-labelled nucleic acid probes for the visualization by in situ hybridization (ISH) of specific nucleotide sequences in sections of formalin fixed, paraffin-embedded tissue using the automated BOND system (includes BOND-MAX, BOND-III, and BOND-PRIME systems). The clinical interpretation of any staining or its absence should be complemented by morphological studies and proper controls and should be evaluated within the context of the patient's clinical history and other diagnostic tests by a qualified pathologist. Anti-Fluorescein Antibody is intended to be used with other devices for visualization of staining and as such, qualitative or semi-quantitative diagnostic function including specific disease indication and intended use population is				
		described within the associated device labelling as required for that device.				
	AR0833	BOND Ready-to-Use Anti- Fluorescein Antibody 3.75 mL	Rule 5(a)	50553313ISHAFL00006RK		
AR0833, 3.75mL	Intended Purpose:	For in vitro diagnostic use. Anti-Fluorescein Antibody is intaction acid probes for the visualization nucleotide sequences in section using the automated BOND systems). The clinical interpretation of arcomplemented by morphologic evaluated within the context of diagnostic tests by a qualified particular and asfunction including specific disedescribed within the associated	n by in situ hybridizens of formalin fixed stem (includes BON my staining or its abscal studies and project fithe patient's clinicathologist. Itended to be used such, qualitative of ase indication and	zation (ISH) of specific d, paraffin-embedded tissue ID-MAX, BOND-III, and BOND-ISENCE should be per controls and should be cal history and other with other devices for r semi-quantitative diagnostic intended use population is		



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Product (Catalogue) Code & Pack Size	SAP Code	IFU Product Name	Risk Classification Rule	Basic UDI-DI
	AR0584	BOND Ready-to-Use Anti- Biotin Antibody	Rule 5(a)	50553313ISHABI00006N8
AR0584, 7.5mL	Intended Purpose:	For in vitro diagnostic use. Anti-Biotin Antibody is intended for the visualization by in situal sequences in sections of formal automated BOND system (inclusystems). The clinical interpretation of a complemented by morphologic evaluated within the context of diagnostic tests by a qualified Anti-Biotin Antibody is intended of staining and as such, qualitatincluding specific disease indiction within the associated device less sections.	hybridization (ISH) of alin fixed, paraffin-of udes BOND-MAX, Entry staining or its aligned at the patient's clinical pathologist. Bed to be used with of attive or semi-quantication and intended	of specific nucleotide embedded tissue using the BOND-III, and BOND-PRIME osence should be per controls and should be cal history and other other devices for visualization itative diagnostic function I use population is described
	AR0633	BOND Ready-to-Use	Rule 5(a)	50553313ISHSTW00006G9
AR0633 3.75mL AR0633 Stringency Wash Solution For in vitro diagnostic use. The Stringency Wash Solution is reduce non-specific hybridizatio on sections of formalin fixed, particular by morphologic evaluated within the context of diagnostic tests by a qualified particular by The Stringency Wash Solution is situ hybridization procedures and diagnostic function including specific population is described within the that device.		ion when performing paraffin-embedded -MAX, BOND-III, and staining or its absect and proof the patient's clinical studies and property is intended to be upond as such, qualitatical pecific disease indi	ng in situ hybridization (ISH) tissue using the automated d BOND-PRIME systems). seence should be per controls and should be cal history and other sed with other devices for in ative or semi-quantitative cation and intended use	



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	AR9037	BOND Hybridization Solution	Rule 5(a)	50553313RNAHYB000062Z
AR9037, 100mL	Intended Purpose:	BOND HILL III III CARL THE ALL III III III III III III III III III		formalin fixed, paraffin- ax or BOND-III systems. asence should be per controls and should be cal history and other ed with other devices for in ative or semi-quantitative cation and intended use
	AR9222	BOND Dewax Solution	Rule 5(a)	50553313DEWAXS00005X6
AR9222, 1000mL	Intended Purpose:	For in vitro diagnostic use BOND Dewax Solution is a real removal of paraffin wax from a immunohistochemistry (IHC) of automated BOND-MAX or BOI The clinical interpretation of a complemented by morphologic evaluated within the context of diagnostic tests by a qualified BOND Dewax Solution is inten IHC and ISH procedures and as function including specific dise described within the associate	formalin-fixed, para or in situ hybridizati ND-III systems. ny staining or its ab ical studies using pr of the patient's clini pathologist. ded to be used for a such, qualitative of ease indication and	affin-embedded tissue, during on (ISH) procedures using the assence should be roper controls and should be call history and other assemble preparation within or semi-quantitative diagnostic intended use population is



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Product (Catalogue) Code & Pack Size	SAP Code	IFU Product Name	Risk Classification Rule	Basic UDI-DI
	AR9352	Bond Primary Antibody Diluent	Rule 5(a)	50553313PADILU00005QP
AR9352, 500mL	Intended Purpose:	For <i>in vitro</i> diagnostic use. BOND Primary Antibody Diluent is intended for use as a diluent of individual antibody concentrates in immunohistochemical (IHC) procedures on sections of formalin fixed, paraffin-embedded tissue using the automated BOND-MAX or BOND-III systems. The clinical interpretation of any staining or its absence should be complemented by morphological studies using proper controls and should be evaluated within the context of the patient's clinical history and other diagnostic tests by a qualified pathologist. BOND Primary Antibody Diluent is intended to be used with other devices during IHC procedures and as such, qualitative or semi-quantitative diagnostic function including specific disease indication and intended use population is described within the associated device labelling as required for that device. BOND Primary Antibody Diluent is not to be used for the reconstitution of lyophilized antibodies.		
	AR9551	Bond Enzyme Pre-treatment Kit	Rule 5(a)	50553313ENZPTK00005E3
AR9551, 1 kit	Intended Purpose:	For in vitro diagnostic use. BOND Enzyme Pre-treatment enzyme diluent, which require of sections of formalin fixed, properties of sections	e mixing, and is inte paraffin-embedded -MAX, BOND-III, an ny staining or its ab ical studies using pr of the patient's clini pathologist. Kit is intended to be (IHC) and in situ hy ni-quantitative diag	nded for enzymatic digestion tissue using the automated d BOND-PRIME systems). Usence should be roper controls and should be call history and other devices (Vbridization (ISH) procedures nostic function including ulation is described within the



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Product (Catalogue) Code & Pack Size	SAP Code	IFU Product Name	Risk Classification Rule	Basic UDI-DI
	AR9590	BOND Wash Solution 10X Concentrate	Rule 5(a)	5055331WSCONC00005CG
AR9590, 1000mL	Intended Purpose:	systems. The clinical interpretation of complemented by morpholo evaluated within the contex diagnostic tests by a qualified BOND Wash Solution 10X Codevices during immunohistor procedures and as such, qualified procedures and as such as su	I is intended for wa ssue using the autor f any staining or its ogical studies using t of the patient's clied ad pathologist. oncentrate is intend ochemistry (IHC) and alitative or semi-quadication and intend	shing sections of formalin mated BOND-MAX or BOND-III absence should be proper controls and should be nical history and other led to be used with other d in situ hybridization (ISH) antitative diagnostic function led use population is described
	AR9640	BOND Epitope Retrieval Solution 2	Rule 5(a)	50553313ERSOL200005VY
AR9640, 1000mL	Intended Purpose:	For in vitro diagnostic use. BOND Epitope Retrieval Solu intended for the heat-induct paraffin-embedded tissue us systems. The clinical interpretation of complemented by morpholo evaluated within the contex diagnostic tests by a qualified BOND Epitope Retrieval Solu during immunohistochemist procedures and as such, qualifications in the context of t	ed epitope retrieval sing the automated f any staining or its ogical studies using t of the patient's clied ad pathologist. ution 2 is intended to cry (IHC) and in situ- alitative or semi-quadication and intended	absence should be proper controls and should be nical history and other to be used with other devices hybridization (ISH) antitative diagnostic function ed use population is described



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Product (Catalogue) Code & Pack Size	SAP Code	IFU Product Name	Risk Classification Rule	Basic UDI-DI
	AR9961	BOND Epitope Retrieval Solution 1	Rule 5(a)	50553313ERSOL200005VK
AR9961, 1000mL	Intended Purpose:	For in vitro diagnostic use. BOND Epitope Retrieval Solution 1 is a ready to use epitope retrieval solution intended for the heat-induced epitope retrieval (HIER) of formalin fixed, paraffin-embedded tissue using the automated BOND-MAX or BOND-III systems. The clinical interpretation of any staining or its absence should be complemented by morphological studies using proper controls and should be evaluated within the context of the patient's clinical history and other diagnostic tests by a qualified pathologist. BOND Epitope Retrieval Solution 1 is intended to be used with other devices during immunohistochemistry (IHC) and in situ hybridization (ISH) procedures and as such, qualitative or semi-quantitative diagnostic function including specific disease indication and intended use population is described within the associated device labelling as required for that device.		
	ΔR9/132	ROND DAR Enhancer	Rule 5(a)	50553313BDABEN00005YV
AR9432 BOND DAB Enhancer Rule 5(a) 50553313BDA Intended Purpose: BOND DAB Enhancer is intended for use as a ready to use solution intensifies the DAB staining during immunohistochemical (IHC) prosections of formalin fixed, paraffin-embedded tissue using the automorphisms becomplemented by morphological studies using proper controls are evaluated within the context of the patient's clinical history and of diagnostic tests by a qualified pathologist. BOND DAB Enhancer is intended to be used with other devices for of staining and as such, qualitative or semi-quantitative diagnostic including specific disease indication and intended use population within the associated device labelling as required for that device.		ly to use solution that hemical (IHC) procedures on sue using the automated d BOND-PRIME systems). It is sence should be roper controls and should be call history and other other devices for visualization itative diagnostic function are solution is described		



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Product (Catalogue) Code & Pack Size	SAP Code	IFU Product Name	Risk Classification Rule	Basic UDI-DI
	AR0084	BOND-PRIME Dewax Solution	Rule 5(a)	50553313PRIDEW0005M9
AR0084, 1L	Intended Purpose:	For in vitro diagnostic use. BOND-PRIME Dewax Solution is a ready to use dewaxing solution intended for removal of paraffin wax from formalin-fixed, paraffin-embedded tissue, during immunohistochemistry (IHC) or in situ hybridization (ISH) procedures using the automated BOND-PRIME system. The clinical interpretation of any staining or its absence should be complemented by morphological studies using proper controls and should be evaluated within the context of the patient's clinical history and other diagnostic tests by a qualified pathologist. BOND-PRIME Dewax Solution is intended to be used for sample preparation within IHC and ISH procedures and as such, qualitative or semi-quantitative diagnostic function including specific disease indication and intended use population is described within the associated device labelling as required for that device.		
	AR0085	BOND-PRIME Wash Solution Concentrate	Rule 5(a)	50553313PRIWAS0005UC
AR0085, 1L	Intended Purpose:	For in vitro diagnostic use. BOND-PRIME Wash Solution Crequiring initial dilution, and is paraffin-embedded tissue usin The clinical interpretation of a complemented by morpholog evaluated within the context of diagnostic tests by a qualified BOND-PRIME Wash Solution Context of devices during immunohistoch procedures and as such, qualificulating specific disease indication within the associated device is	s intended for washing the automated B ny staining or its ablical studies using profithe patient's clinical pathologist. Concentrate is intended in the pative or semi-quant cation and intended	oning sections of formalin fixed, OND-PRIME system. In the section of the section



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Product (Catalogue) Code & Pack Size	SAP Code	IFU Product Name	Risk Classification Rule	Basic UDI-DI	
	AR0086	BOND-PRIME Epitope Retrieval Solution 1	Rule 5(a)	50553313PRIEP10005DJ	
AR0086, 1L	Intended Purpose:	For in vitro diagnostic use. BOND-PRIME Epitope Retrieval Solution 1 is a ready to use epitope retrieval solution intended for the heat-induced epitope retrieval (HIER) of formalin fixed, paraffin-embedded tissue using the automated BOND-PRIME system. The clinical interpretation of any staining or its absence should be complemented by morphological studies using proper controls and should be evaluated within the context of the patient's clinical history and other diagnostic tests by a qualified pathologist. BOND-PRIME Epitope Retrieval Solution 1 is intended to be used with other devices during immunohistochemistry (IHC) and in situ hybridization (ISH) procedures and as such, qualitative or semi-quantitative diagnostic function including specific disease indication and intended use population is described within the associated device labelling as required for that device.			
	AR0087	BOND-PRIME Epitope Retrieval Solution 2	Rule 5(a)	50553313PRIEP20005DV	
Intended Purpose: For in vitro diagnostic use. BOND-PRIME Epitope Retrieval Solution 2 is a ready to use ep solution intended for the heat-induced epitope retrieval (HIEF fixed, paraffin-embedded tissue using the automated BOND-PT The clinical interpretation of any staining or its absence should complemented by morphological studies using proper control evaluated within the context of the patient's clinical history and diagnostic tests by a qualified pathologist. BOND-PRIME Epitope Retrieval Solution 2 is intended to be used devices during immunohistochemistry (IHC) and in situ hybrid procedures and as such, qualitative or semi-quantitative diagnincluding specific disease indication and intended use populat within the associated device labelling as required for that device series are such as such as such as such as a such as such a		etrieval (HIER) of formalin ated BOND-PRIME system. It is sence should be reper controls and should be call history and other anded to be used with other in situ hybridization (ISH) titative diagnostic function are use population is described			



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Product (Catalogue) Code & Pack Size	SAP Code	IFU Product Name	Risk Classification Rule	Basic UDI-DI
	AR0096	BOND-PRIME Hematoxylin	Rule 5(a)	50553313PRIHEM0005KX
AR0096, 30mL	Intended Purpose:	For in vitro diagnostic use. BOND-PRIME Hematoxylin is a (blue) counterstaining of form immunohistochemistry (IHC) a automated BOND-PRIME auto The clinical interpretation of a complemented by morpholog evaluated within the context of diagnostic tests by a qualified BOND-PRIME Hematoxylin is in visualization of staining and as function including specific disedescribed within the associated	alin-fixed, paraffin- and in situ hybridiza mated staining syst ny staining or its ab ical studies and pro of the patient's clini- pathologist. ntended to be used s such, qualitative o ease indication and	embedded tissue in tion (ISH) using the tem. seem. seence should be per controls and should be cal history and other with other devices for r semi-quantitative diagnostic intended use population is



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Appendix 2 Applicable Standards

Regulatory Authority/Group	Standard/Guidance Title and Revision
EU IVDD Harmonised Standards	 EN ISO 18113-1:2011 In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Terms, definitions and general requirements (British Standard) EN ISO 18113-2:2011 In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). In vitro diagnostic reagents for professional use (British Standard) EN ISO 23640:2015 In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents EN ISO 15223-1:2016 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements. EN 13975:2003 Sampling procedures used for acceptance testing of in vitro diagnostic medical devices. Statistical aspects
EU IVDR Harmonised Standards	EN ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes
Other ISO Standards	EN ISO 14971:2019 Medical devices — Application of risk management to medical devices