1 Manufacturer and / or Authorised Representative details.

Manufacturer:	**Authorised Representative:**
Leica Biosystems Newcastle Ltd Balliol Business Park West Benton Lane Newcastle upon Tyne NE12 8EW United Kingdom Tel: +44 (0)191 215 0567 Fax: +44 (0)191 215 1152 Single Registration Number (SRN): GB-MF-000020595	CEpartner4U BV Esdoornlaan 13 3951 DB Maarn The Netherlands Tel: +31 343 442 524 Fax: +31 343 442 162 E-mail: office@cepartner4u.com 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

8	**Notified Body, Conformity Assessment Procedure & Certificate Details.**	
	Name of notified body: Identification number of notified body:	In accordance with Annex VIII, Rule 5(a) of the IVDR the devices listed in Appendix 1 have been assigned the risk classification of A. Conformity assessment by a notified body is therefore not applicable.
	Conformity assessment procedure:	Self Declaration of Conformity based on Annex II: Technical Documentation and Annex III: Technical Documentation on Post-Market Surveillance.
	Certificates issued:	N/A
9	**Additional information.**	
	N/A	
10	**Issuing and Signing of Declaration.**	
	Signed on behalf of the manufacturer by:	
	Signature:	DocuSigned by: Laura Tracy Signer Name: Laura Tracy Signing Reason: I approve this document Signing Time: 31 March 2022 | 7:28:31 AM PDT C4B2D6F558A342E1B5DDD387086C4006
	Name:	Laura Tracy
	Position:	Director, Global Regulatory Affairs - Advanced Staining
	Date of issue:	31 March 2022
	Place of issue:	Leica Biosystems Newcastle Ltd

Appendix 1
Device Details

Product (Catalogue) Code & Pack Size	SAP Code	IFU Product Name	Risk Classification Rule	Basic UDI-DI
AR0222, 15mL	AR0222	BOND Ready-to-Use Anti-Fluorescein Antibody 15 mL	Rule 5(a)	50553313ISHAFL00006RK
	Intended Purpose:	For *in vitro* 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, 3.75mL	AR0833	BOND Ready-to-Use Anti-Fluorescein Antibody 3.75 mL	Rule 5(a)	50553313ISHAFL00006RK
	Intended Purpose:	For *in vitro* 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.		

Product (Catalogue) Code & Pack Size	SAP Code	IFU Product Name	Risk Classification Rule	Basic UDI-DI
AR0584, 7.5mL	AR0584	BOND Ready-to-Use Anti-Biotin Antibody	Rule 5(a)	50553313ISHABI00006N8
	Intended Purpose:	For *in vitro* diagnostic use. Anti-Biotin Antibody is intended for use with biotin-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-Biotin 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.		
AR0633 3.75mL	AR0633	BOND Ready-to-Use Stringency Wash Solution	Rule 5(a)	50553313ISHSTW00006G9
	Intended Purpose:	For *in vitro* diagnostic use. The Stringency Wash Solution is intended for use with nucleic acid probes to reduce non-specific hybridization when performing *in situ* hybridization (ISH) on 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. The Stringency Wash Solution is intended to be used with other devices for *in situ* hybridization 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.		

Product (Catalogue) Code & Pack Size	SAP Code	IFU Product Name	Risk Classification Rule	Basic UDI-DI
AR9037, 100mL	AR9037	BOND Hybridization Solution	Rule 5(a)	50553313RNAHYB000062Z
	Intended Purpose:	For *in vitro* diagnostic use. BOND Hybridization Solution is intended to be used as a diluent of *in situ* hybridization (ISH) probes for use 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 and proper controls and should be evaluated within the context of the patient's clinical history and other diagnostic tests by a qualified pathologist. BOND Hybridization Solution is intended to be used with other devices for in situ hybridization 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.		
AR9222, 1000mL	AR9222	BOND Dewax Solution	Rule 5(a)	50553313DEWAXS00005X6
	Intended Purpose:	For *in vitro* diagnostic use BOND 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-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 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.		

Product (Catalogue) Code & Pack Size	SAP Code	IFU Product Name	Risk Classification Rule	Basic UDI-DI
AR9352, 500mL	AR9352	Bond Primary Antibody Diluent	Rule 5(a)	50553313PADILU00005QP
	Intended Purpose:	For *in vitro* 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, 1 kit	AR9551	Bond Enzyme Pre-treatment Kit	Rule 5(a)	50553313ENZPTK00005E3
	Intended Purpose:	For *in vitro* diagnostic use. BOND Enzyme Pre-treatment Kit consists of an enzyme concentrate and an enzyme diluent, which require mixing, and is intended for enzymatic digestion of 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 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 Enzyme Pre-treatment Kit 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.		

Product (Catalogue) Code & Pack Size	SAP Code	IFU Product Name	Risk Classification Rule	Basic UDI-DI
AR9590, 1000mL	AR9590	BOND Wash Solution 10X Concentrate	Rule 5(a)	5055331WSCONC00005CG
	Intended Purpose:	For *in vitro* diagnostic use. BOND Wash Solution 10X Concentrate is a concentrated buffer solution, requiring initial dilution, and is intended for washing 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 Wash Solution 10X Concentrate 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.		
AR9640, 1000mL	AR9640	BOND Epitope Retrieval Solution 2	Rule 5(a)	50553313ERSOL200005VY
	Intended Purpose:	For *in vitro* diagnostic use. BOND Epitope Retrieval Solution 2 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 2 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.		

Product (Catalogue) Code & Pack Size	SAP Code	IFU Product Name	Risk Classification Rule	Basic UDI-DI
AR9961, 1000mL	AR9961	BOND Epitope Retrieval Solution 1	Rule 5(a)	50553313ERSOL200005VK
	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.		
AR9432, 30mL	AR9432	BOND DAB Enhancer	Rule 5(a)	50553313BDABEN00005YV
	Intended Purpose:	For *in vitro* diagnostic use. BOND DAB Enhancer is intended for use as a ready to use solution that intensifies the DAB staining during immunohistochemical (IHC) procedures on 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 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 DAB Enhancer 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.		

Product (Catalogue) Code & Pack Size	SAP Code	IFU Product Name	Risk Classification Rule	Basic UDI-DI
AR0084, 1L	AR0084	BOND-PRIME Dewax Solution	Rule 5(a)	50553313PRIDEW0005M9
	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, 1L	AR0085	BOND-PRIME Wash Solution Concentrate	Rule 5(a)	50553313PRIWAS0005UC
	Intended Purpose:	For *in vitro* diagnostic use. BOND-PRIME Wash Solution Concentrate is a concentrated buffer solution, requiring initial dilution, and is intended for washing sections 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 Wash Solution Concentrate 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.		

Product (Catalogue) Code & Pack Size	SAP Code	IFU Product Name	Risk Classification Rule	Basic UDI-DI
AR0086, 1L	AR0086	BOND-PRIME Epitope Retrieval Solution 1	Rule 5(a)	50553313PRIEP10005DJ
	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, 1L	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 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 2 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.		

Product (Catalogue) Code & Pack Size	SAP Code	IFU Product Name	Risk Classification Rule	Basic UDI-DI
AR0096, 30mL	AR0096	BOND-PRIME Hematoxylin	Rule 5(a)	50553313PRIHEM0005KX
	Intended Purpose:	For *in vitro* diagnostic use. BOND-PRIME Hematoxylin is a ready to use reagent that facilitates cell nuclei (blue) counterstaining of formalin-fixed, paraffin-embedded tissue in immunohistochemistry (IHC) and in situ hybridization (ISH) using the automated BOND-PRIME automated staining system. 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. BOND-PRIME Hematoxylin 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.		

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