Advancing Cancer Diagnostics
Improving Lives

Declaration of Conformity

We declare, under our sole responsibility, that the product listed below fulfills the requirements specified in Regulation (EU) 2017/746 on in-vitro diagnostic (IVD) medical devices.

Manufacturer's Name and Business Address:	Leica Biosystems Melbourne Pty Ltd 495 Blackburn Road Mt Waverley Victoria 3149, AUSTRALIA
Manufacturer Single Registration Number (SRN):	AU-MF-000016740
European Representative:	CEpartner4U BV Esdoornlaan 13 3951 DB Maarn The Netherlands
European Representative Single Registration Number (SRN):	NL-AR-000000111
Product Name:	BOND-MAX processing module and associated components listed in the attached device Schedule A
Basic UDI-DI:	9349458001D9
Risk Class:	Class A – Rule 5 Annex VIII of Regulation (EU) 2017/746
Conformity Assessment Route:	Annex IV, in combination with Annex II and Annex III
Object of the declaration:	
Intended Use:	The BOND system automates clinical protocols for immunostaining of pathology specimens mounted on microscope slides. Microscope slides subsequently undergo interpretation by a qualified healthcare professional to aid diagnosis.

The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:

Electromagnetic Compatibility (2014/30/EU)	Restriction on the Use of Certain Hazardous Substance in Electrical & Electronic Equipment (2011/65/EU)
Waste electrical & Electronic Equipment (2012/19/EU)	Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices

The following standards and technical documentation have been applied:

EN ISO 13485:2016	Medical Device - Quality Management Systems – Requirements for Regulatory Purposes
ISO 14971:2019	Medical devices - Application of risk management to medical device
ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer Part 1: General requirements
EN 61326-1:2013 (IEC 61326-1:2012, Edition 2.0)	Electrical equipment for measurement, control and laboratory use- EMC requirements. Part 1: General requirements.
EN 61326-2-6:2013 (IEC 61326-2-6:2012 Edition 2.0)	Electrical equipment for measurement, control and laboratory use-EMC requirements- Part 2-6: Particular requirements- In vitro diagnostic (IVD) medical equipment.
EN 61010-1: 2010 (UL/IEC 61010-1 Edition.3.0)	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirements
EN 61010-2-010: 2014 (IEC 61010-2-010 Edition.3.0)	Safety requirements for electrical equipment for measurement, control, and laboratory use Part. 2-010, Particular requirements for laboratory equipment for the heating of materials
IEC 61010-2-081 2009 Edition.1; Amendement1	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
EN 61010-2-101: 2017 (IEC 61010-2-101 Edition.2.0)	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Safety requirements for in vitro diagnostic (IVD) medical equipment

ANSI/AAMI/IEC 62366-1: 2015	Medical Devices - Part 1: Application Of Usability Engineering To Medical Devices
ANSI 62304: 2006/A1 2016	Medical Device Software - Software Life Cycle Processes
EN 13975: 2003	Sampling procedures used for acceptance testing of in vitro diagnostic medical devices. Statistical aspects
EN 13612: 2002	Performance Evaluation Of In Vitro Diagnostic Medical Devices
EN 18113: 2011	Labelling Requirements for IVD Medical Devices

Signed for and on behalf of:

DocuSigned by:
Yuvesh Jain
Signer Name: Yuvesh Jain
Signing Reason: I approve this document
Signing Time: 20-Dec-2023 | 21:19:17 PST
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Yuvesh Jain
RC Manager
Leica Biosystems Melbourne Pty Ltd

SCHEDULE A

Component/Accessory Description	Catalogue Number
BOND-MAX Processing Module	49.0051
BOND System Control Kit (6.0/W10 loT) containing:	21.2793
BOND System Control Kit (7)	49.0644
BOND Controller (6.0/W10 loT)	S21.4621
BOND Controller (7)	S49.4524
BOND-ADVANCE Terminal (6.0/W10 loT)	S21.4622
BOND-ADVANCE Terminal (7)	49.4525
BOND-ADVANCE Controller (6.0)	S21.4623
BOND-ADVANCE Controller (7)	49.4526
BOND Universal Covertiles (pack of 160)	S21.4611
BOND Universal Covertiles – 100 Pack	S21.2001
BOND Slide Labels and Printing Ribbon	S21.4564
BOND Cognitive Slide Labeller	S21.4605
BOND Printer Ribbon & Labels Cxi (1 Pack)	S21.4604
BOND Printer Ribbon & Labels Cxi (6 Pack)	S21.4610
BOND Handheld Barcode Scanner	S21.2802
BOND Mixing Stations (5 pack)	S21.1971
ZD421 BOND Slide Label Printer Spare	S21.4632

Revision No.	Date	Summary of Changes
A01	18 Feb 2022	Initial release and date of first compliance with (EU) 2017/746
A02	21 Apr 2023	Update to include the intended use
A03	21 Dec 2023	Replaced S21.4615 with S21.4632 and added additional standards.