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 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-PRIME 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)	In Vitro Diagnostic Medical Devices Regulation 2017/746

The following standards have been applied:

EN 61326-1:2021 (IEC 61326-1:2020)	Electrical equipment for measurement, control and laboratory use- EMC requirements. Part 1: General requirements.
EN 61326-2-6:2021 (IEC 61326-2-6:2020)	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, (IEC 61010-1:2010/AMD1:2016)	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirements
IEC 61010-2-010:2019	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 61010-2-081:2019	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
IEC 61010-2-101:2018	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for In vitro diagnostic (IVD) medical equipment

Signed for and on behalf of:

DocuSigned by:
Sandeep Chollangi
Signer Name: Sandeep Chollangi
Signing Reason: I approve this document
Signing Time: 21-Apr-2023 | 15:53:29 AEST
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Sandeep Chollangi
RA Manager
Leica Biosystems Melbourne Pty Ltd

SCHEDULE A

Component/Accessory Description	Catalogue Number
BOND-PRIME Processing Module	91.0021
BOND System Control Kit (7)	49.0644
BOND Controller (7)	S49.4524
BOND-ADVANCE Terminal (7)	49.4525
BOND-ADVANCE Controller (7)	49.4526
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
Zebra GX430t Label Printer Spare	S21.4615
BOND-PRIME ARC Refresh Kit	91.1592

Revision No.	Date	Summary of Changes
A01	18 Feb 2022	Initial release and date of first compliance with (EU) 2017/746
A02	1 Jun 2022	Update BOND-PRIME Catalogue Number
A03	21 April 2023	Update to include the intended use