


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:	

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 61326-1:2013
(IEC 61326-1:2012 Edition 2.0)

Electrical equipment for measurement,
control and laboratory use- EMC
requirements. Part 1: General requirements.
Electrical equipment for measurement,
control and laboratory use-EMC
requirements- Part 2-6: Particular
requirements- In vitro diagnostic (IVD)
medical equipment.

EN 61326-2-6:2013
(IEC 61326-2-6:2012 Edition 2.0)

UL/IEC 61010-1, Edition 3.0

Safety requirements for electrical equipment
for measurement, control, and laboratory use
Part 1: General requirements

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, Edition 1.1

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 Edition 2.0

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:

Diana Cundall
RA 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 IoT) containing:	21.2793
BOND System Control Kit (7)	49.0644
BOND Controller (6.0/W10 IoT)	S21.4621
BOND Controller (7)	S49.4524
BOND-ADVANCE Terminal (6.0/W10 IoT)	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
Zebra GX430t Label Printer Spare	S21.4615

Revision No.	Date	Summary of Changes
A01	18 Feb 2022	Initial release and date of first compliance with (EU) 2017/746

