

## Declaration of Conformity

We declare, under our sole responsibility, that the product listed below conforms to the provisions of the European Council Directive 98/79/EC of 27 October 1998 concerning in-vitro diagnostic (IVD) medical devices.

According to Article 9 Conformity assessment procedure, Leica Biosystems Melbourne Pty Ltd shall apply the CE mark to the identified IVD by complying with all Essential requirement (Annex I) of the IVD Directive 98/79/EC and fulfil the obligations imposed by Annex III, Section 1 to section 5 and Annex IV, Section 1 to 3 and Section 5 respectively to demonstrate compliance to Full Quality Assurance System of the IVD Directive 98/79/EC.

**Manufacturer's Name and Business Address:**

Leica Biosystems Melbourne Pty Ltd  
495 Blackburn Road  
Mount Waverley  
VIC 3149, Australia

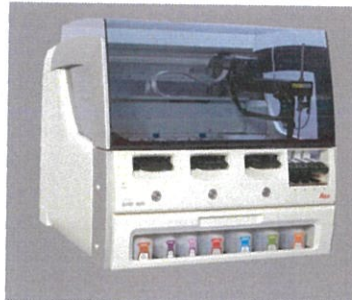
**European Representative:**

CEpartner4U  
Esdoornlaan 13  
3951 DB Maarn  
The Netherlands

**Product Name:**

BOND-MAX processing module and  
associated components listed in the attached  
device Schedule A

**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)

Waste electrical & Electronic Equipment  
(2012/19/EU)

Restriction on the Use of Certain Hazardous  
Substance in Electrical & Electronic  
Equipment (2011/65/EU)  
In Vitro Diagnostic Medical Devices  
(98/79/EC)

**The following harmonised 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.
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 50581:2012	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
UL/IEC 61010-1, Edition 2.0	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirements
IEC 61010-2-010, Edition 2.0	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.1	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:

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Adrienne Hardisty

RA/QA Manager  
Leica Biosystems Melbourne Pty Ltd

Date: 9 Dec 2020



## SCHEDULE A

Component/Accessory Description	Catalogue Number
BOND-MAX Processing Module	49.0051
BOND System Control Kit (6.0/W10 IoT) containing: Slide Labeller Ethernet switch Computer BOND System Control Add Kit (which includes handheld barcode scanner and power cable)	21.2793   21.2023 (EUR) 21.2021 (UK)
BOND Controller (6.0/W10 IoT)	S21.4621
BOND-ADVANCE Terminal (6.0/W10 IoT)	S21.4622
BOND-ADVANCE Controller (6.0)	S21.4623
BOND System HR 8 port Ethernet Switch	S21.4577
BOND System HR 16 port Ethernet Switch	S21.4578
BOND Server Add Kit (UK)	21.2024
BOND Server Add Kit (EUR)	21.2026
BOND PC Add Kit (UK)	21.2027
BOND PC Add Kit (EUR)	21.2029
BOND PM Add Kit (UK)	21.1992
BOND PM Add Kit (EUR)	21.1994
Windows 10 IoT Licence	S49.6481
BOND LIS-ip Licence Key (5.0+)	S49.4570
Consumables	Catalogue Number
BOND Universal Covertiles (pack of 160)	S21.4611
BOND Universal Covertiles – 100 Pack	S21.2001
BOND Slide Labels and Printing Ribbon	S21.4564
BOND Slide Labeler Cleaning Pen	S21.1913
BOND Mixing Stations	S21.1971
BOND Aspirating Probe	S21.0605
BOND Cognitive Slide Labeller	S21.4605
BOND Printer Ribbon & Labels Cxi (1 Pack)	S21.4604
BOND Printer Ribbon & Labels Cxi (6 Pack)	S21.4610

Consumables	Catalogue Number
BOND Handheld Barcode Scanner	S21.2802
BOND Covertile Cleaning Rack	S21.4588
BOND Slide Tray	S21.4586
BOND Reagent Tray	S21.1003
BOND Mixing Stations (5 pack)	S21.1971
BOND Syringe (for 9-port pump)	S21.2131
BOND-III Syringes (4 pack)	S21.4565
Zebra GX430t Label Printer Spare	S21.4615