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 medical devices.

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|---|---|
| **Manufacturer's Name and Business Address:** | Leica Biosystems Melbourne Pty Ltd<br>495 Blackburn Road<br>Mt Waverley<br>Victoria 3149, AUSTRALIA |
| **Manufacturer Single Registration Number (SRN):** | AU-MF-000016740 |
| **European Representative:** | CEpartner4U BV<br>Esdoornlaan 13<br>3951 DB Maarn<br>The Netherlands |
| **European Representative Single Registration Number (SRN):** | NL-AR-000000111 |
| **Product Name:** | BOND-III processing module and associated components listed in 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:**

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| 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:**

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|---|---|
| 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 |

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|---|---|
| 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 | 21:15:18 PST
FA6267834E5A445ABD7CBA909C044089

**Yuvesh Jain**
**RC Manager**
**Leica Biosystems Melbourne Pty Ltd**

## SCHEDULE A

| Component/Accessory Description | Catalogue Number |
|---|---|
| BOND-III Processing Module | 21.2201 |
| BOND System Control Kit (6.0/W10 IoT) | 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 |
| 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. |