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-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: 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.

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.

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; 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

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

<table>
<thead>
<tr>
<th>Component/Accessory Description</th>
<th>Catalogue Number</th>
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<tbody>
<tr>
<td>BOND-III Processing Module</td>
<td>21.2201</td>
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<tr>
<td>BOND System Control Kit (6.0/W10 IoT)</td>
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<td>BOND System Control Kit (7)</td>
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<td>BOND Controller (6.0/W10 IoT)</td>
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<td>BOND Slide Labels and Printing Ribbon</td>
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<td>Zebra GX430t Label Printer Spare</td>
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**Revision No.**  
A01  
**Date**  
18 Feb 2022  
**Summary of Changes**  
Initial release and date of first compliance with (EU) 2017/746