Declaration of Conformity


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:
Leica Biosystems Newcastle Ltd
Balliol Business Park West, Benton Lane,
Newcastle Upon Tyne NE12 8EW
United Kingdom

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)
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 (98/79/EC)
The following harmonised standards and technical documentation have been applied:

<table>
<thead>
<tr>
<th>Standard</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>EN 50581:2012</td>
<td>Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances</td>
</tr>
<tr>
<td>UL/IEC 61010-1, Edition 2.0</td>
<td>Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirements</td>
</tr>
<tr>
<td>IEC 61010-2-010, Edition 2.0</td>
<td>Safety requirements for electrical equipment for measurement, control, and laboratory use Part. 2-010, Particular requirements for laboratory equipment for the heating of materials</td>
</tr>
<tr>
<td>IEC 61010-2-081, Edition 1.1</td>
<td>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</td>
</tr>
</tbody>
</table>

Signed for and on behalf of: 

Adrienne Hardisty  
RA/QA Manager  
Leica Biosystems Melbourne Pty Ltd 

Date: 9 Apr 2020
## SCHEDULE A

<table>
<thead>
<tr>
<th>Component/Accessory Description</th>
<th>Catalogue Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>BOND-MAX Processing Module</td>
<td>49.0051</td>
</tr>
<tr>
<td>BOND System Control Kit (6.0.1/W10 IoT) containing:</td>
<td>21.2793</td>
</tr>
<tr>
<td><em>Slide Labeller</em></td>
<td></td>
</tr>
<tr>
<td><em>Ethernet switch</em></td>
<td></td>
</tr>
<tr>
<td><em>Computer</em></td>
<td></td>
</tr>
<tr>
<td>BOND System Control Add Kit (which includes handheld barcode scanner and power cable)</td>
<td>21.2023 (EUR)</td>
</tr>
<tr>
<td></td>
<td>21.2021 (UK)</td>
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<tr>
<td>BOND-ADVANCE Controller (6.0.1/W10 IoT)</td>
<td>S21.4623</td>
</tr>
<tr>
<td>BOND Controller (6.0.1/W10 IoT)</td>
<td>S21.4621</td>
</tr>
<tr>
<td>BOND-ADVANCE Terminal (6.0.1/W10 IoT)</td>
<td>S21.4622</td>
</tr>
<tr>
<td>BOND System HR 8 port Ethernet Switch</td>
<td>S21.4577</td>
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<tr>
<td>BOND System HR 16 port Ethernet Switch</td>
<td>S21.4578</td>
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<tr>
<td>BOND Server Add Kit (UK)</td>
<td>21.2024</td>
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<tr>
<td>BOND Server Add Kit (EUR)</td>
<td>21.2026</td>
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<tr>
<td>BOND PC Add Kit (UK)</td>
<td>21.2027</td>
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<tr>
<td>BOND PC Add Kit (EUR)</td>
<td>21.2029</td>
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<tr>
<td>BOND PM Add Kit (UK)</td>
<td>21.1992</td>
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<td>BOND PM Add Kit (EUR)</td>
<td>21.1994</td>
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<tr>
<td>Windows 10 IoT Licence</td>
<td>S49.6481</td>
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<tr>
<td>BOND LIS-ip Licence Key (5.0+)</td>
<td>S49.4570</td>
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### Consumables

<table>
<thead>
<tr>
<th>Consumables</th>
<th>Catalogue Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>BOND Universal Covertiles (pack of 160)</td>
<td>S21.4611</td>
</tr>
<tr>
<td>BOND Slide Labels and Printing Ribbon</td>
<td>S21.4564</td>
</tr>
<tr>
<td>BOND Slide Labeler Cleaning Pen</td>
<td>S21.1913</td>
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<tr>
<td>BOND Mixing Stations</td>
<td>S21.1971</td>
</tr>
<tr>
<td>BOND Aspirating Probe</td>
<td>S21.0605</td>
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<tr>
<td>BOND Cognitive Slide Labeller</td>
<td>S21.4605</td>
</tr>
<tr>
<td>BOND Printer Ribbon &amp; Labels Cxi (1 Pack)</td>
<td>S21.4604</td>
</tr>
<tr>
<td>BOND Printer Ribbon &amp; Labels Cxi (6 Pack)</td>
<td>S21.4610</td>
</tr>
<tr>
<td>Consumables</td>
<td>Catalogue Number</td>
</tr>
<tr>
<td>-----------------------------------------</td>
<td>------------------</td>
</tr>
<tr>
<td>BOND Handheld Barcode Scanner</td>
<td>S21.2802</td>
</tr>
<tr>
<td>BOND Covertile Cleaning Rack</td>
<td>S21.4588</td>
</tr>
<tr>
<td>BOND Slide Tray</td>
<td>S21.4586</td>
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<tr>
<td>BOND Reagent Tray</td>
<td>S21.1003</td>
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<tr>
<td>BOND Mixing Stations (5 pack)</td>
<td>S21.1971</td>
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<tr>
<td>BOND Syringe (for 9-port pump)</td>
<td>S21.2131</td>
</tr>
<tr>
<td>BOND-III Syringes (4 pack)</td>
<td>S21.4565</td>
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<tr>
<td>Zebra GX430t Label Printer Spare</td>
<td>S21.4615</td>
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</table>