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: ThermoBrite Elite instrument as listed in Schedule A

Basic UDI-DI: 9349458003DD

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:


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.

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; Amendment 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.1.0  
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

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<thead>
<tr>
<th>Component/Accessory Description</th>
<th>Catalogue Number</th>
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<td>ThermoBrite Elite Instrument</td>
<td>3800-007000-001</td>
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<tr>
<th>Revision No.</th>
<th>Date</th>
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<tr>
<td>A01</td>
<td>18 Feb 2022</td>
<td>Initial release and date of first compliance with (EU) 2017/746</td>
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