Advancing Cancer Diagnostics
Improving Lives

Declaration of Conformity

We declare, under our sole responsibility, that the product listed below fulfills the requirements specified in Regultion (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:

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.
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:

DocuSigned by:
Diana Cundall
Signer Name: Diana Cundall
Signing Reason: I approve this document
Signing Time: 18-Feb-2022 | 16:13 AEDT
6E73768C42C340209427BC8AA723578F

Diana Cundall
RA Manager
Leica Biosystems Melbourne Pty Ltd

SCHEDULE A

Component/Accessory Description	Catalogue Number
ThermoBrite Elite Instrument	3800-007000-001

Revision No.	Date	Summary of Changes
A01	18 Feb 2022	Initial release and date of first compliance with (EU) 2017/746