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.

| | |
|---|---|
| **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:** | HistoCore PELORIS 3 and associated components listed in the attached Device Schedule A |
| **Basic UDI-DI:** | 9349458002DB |
| **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:**

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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:**

| | |
|---|---|
| EN 61326-1:2013<br>(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<br>(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<br>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 2.0<br>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: 2001 (Edition 1) + A1:2003 | 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<br>IEC 61010-2-101, Edition 2 | 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 | 16:22 AEDT
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**Diana Cundall**
**RA Manager**
**Leica Biosystems Melbourne Pty Ltd**

## SCHEDULE A

| Component | Catalogue Number |
|---|---|
| HistoCore PELORIS 3 (220-240V) | 45.0001 |
| HistoCore PELORIS 3 (100-120V) | 45.0005 |
| Spaced Basket Kit | S45.4503 |
| Basket Spaced | S45.4505 |
| High Capacity Basket Kit | S45.4504 |
| High Capacity Basket (with dividers) | S45.4506 |

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