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: 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:

- Electromagnetic Compatibility (2014/30/EU) and Restriction on the Use of Certain Hazardous Substance in Electrical & Electronic Equipment (2011/65/EU)
- Waste electrical & Electronic Equipment (2012/19/EU) and Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices

The following standards and technical documentation have been applied:

- IEC 61010-1, Edition 2.0 - Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirements
- 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 - 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 61010-2-010, 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

Signed for and on behalf of:

Diana Cundall
RA Manager
Leica Biosystems Melbourne Pty Ltd
# SCHEDULE A

<table>
<thead>
<tr>
<th>Component</th>
<th>Catalogue Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>HistoCore PELORIS 3 (220-240V)</td>
<td>45.0001</td>
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<tr>
<td>HistoCore PELORIS 3 (100-120V)</td>
<td>45.0005</td>
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<tr>
<td>Spaced Basket Kit</td>
<td>S45.4503</td>
</tr>
<tr>
<td>Basket Spaced</td>
<td>S45.4505</td>
</tr>
<tr>
<td>High Capacity Basket Kit</td>
<td>S45.4504</td>
</tr>
<tr>
<td>High Capacity Basket (with dividers)</td>
<td>S45.4506</td>
</tr>
</tbody>
</table>

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