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 requirements (Annex I) of the IVD Directive 98/79/EC and fulfill 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:
CEpartner4U
Esdoornlaan 13
3951 DB Maarn
The Netherlands

Product Name:
HistoCore PELORIS 3 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:

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.

Electrical equipment for measurement, control and laboratory use - EMC requirements. Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment.

EN 50581:2012
Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

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.

IEC 61010-2-010, Edition 2.0
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.

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
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:

[Signature]

Adrienne Hardisty
RA/QA Manager
Leica Biosystems Melbourne Pty Ltd

Date: 9 Dec 2020
## SCHEDULE A

<table>
<thead>
<tr>
<th>Component</th>
<th>Catalogue Number</th>
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<tbody>
<tr>
<td>HistoCore PELORIS 3 (220-240V)</td>
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<tr>
<td>HistoCore PELORIS 3 (100-120V)</td>
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<td>Spaced Basket Kit</td>
<td>S45.4503</td>
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<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>
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