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 fulfil 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:
Leica Biosystems Newcastle Ltd
Balliol Business Park West, Benton Lane,
Newcastle Upon Tyne NE12 8EW
United Kingdom

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 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
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
IEC 61010-2-101, Edition 1

Signed for and on behalf of:

[Signature]

Date: 27 May 2019

Adrienne Hardisty
RA/QA Manager
Leica Biosystems Melbourne Pty Ltd
## 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>
<td>45.0001</td>
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<tr>
<td>HistoCore PELORIS 3 (100-120V)</td>
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<tr>
<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>
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<tr>
<td>High Capacity Basket (with dividers)</td>
<td>S45.4506</td>
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