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 requirement (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 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.

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

UL/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 1.1  
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  
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:  

.................................................................

Adrienne Hardisty  
RA/QA Manager  
Leica Biosystems Melbourne Pty Ltd

Date: 17 Nov 2017
<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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<td>HistoCore PELORIS 3 (100-120V)</td>
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<tr>
<td>High Capacity Basket Kit</td>
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<tr>
<td>High Capacity Basket (with dividers)</td>
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