

Declaration of Conformity

We declare, under our sole responsibility, that the product listed below conforms to the provisions of the European Council Directive 98/79/EC of 27 October 1998 concerning in-vitro diagnostic medical devices.

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)

Waste electrical & Electronic Equipment
(2012/19/EU)

Restriction on the Use of Certain Hazardous
Substance in Electrical & Electronic
Equipment (2011/65/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:



Date: 17 Nov 2017

Adrienne Hardisty
RA/QA 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

