Advancing Cancer Diagnostics
Improving Lives

Leica BIOSYSTEMS

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 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 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
IEC 61010-1, Edition 2.0 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 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
IEC 61010-2-081: 2001 (Edition 1) + A1:2003	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:

..... Date: 27 May 2019

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