Advancing Cancer Diagnostics
Improving Lives

Declaration of Conformity

We declare, under our sole responsibility, that the product listed below fulfills the requirements specified in Regulation (EU) 2017/746 on in-vitro diagnostic medical devices.

Manufacturer's Name and Business Address:	Leica Biosystems Melbourne Pty Ltd 495 Blackburn Road Mt Waverley Victoria 3149, AUSTRALIA
Manufacturer Single Registration Number (SRN):	AU-MF-000016740
European Representative:	CEpartner4U BV Esdoornlaan 13 3951 DB Maarn The Netherlands
European Representative Single Registration Number (SRN):	NL-AR-000000111
Product Name:	HistoCore PELORIS 3 and associated components listed in the attached Device Schedule A
Basic UDI-DI:	9349458002DB
Risk Class:	Class A – Rule 5 Annex VIII of Regulation (EU) 2017/746
Conformity Assessment Route:	Annex IV, in combination with Annex II and Annex III
Object of the declaration:	
Intended Use:	The HistoCore PELORIS 3 dual retort rapid tissue processor automates preparation of tissue samples for sectioning. This is achieved by transforming fixed specimens into wax infiltrated specimens by exposing them to a sequence of reagents in the tissue processor. Tissue samples subsequently undergo interpretation by a qualified healthcare professional to aid diagnosis.

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)	Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices

The following standards and technical documentation have been applied:

EN ISO 13485:2016	Medical Device – Quality Management Systems – Requirements for Regulatory Purposes
ISO 14971:2019	Medical devices - Application of risk management to medical devices
ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer Part 1: General requirements
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.
IEC 61010-1:2001, Edition 2.0 UL/ IEC 61010-1: 2012, Edition 3.0	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirements
IEC 61010-2-010: 2003, Edition 2.0 IEC 61010-2-010: 2014, 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: 2002, Edition 1 IEC 61010-2-101: 2015, 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.
ANSI/AAMI/IEC 62366-1: 2015	Medical Devices - Part 1: Application Of Usability Engineering To Medical Devices
ANSI 62304:2006/A1 2016	Medical Device Software - Software Life Cycle Processes
EN 13975:2003	Sampling procedures used for acceptance testing of in vitro diagnostic medical devices. Statistical aspects
EN 13612:2002	Performance Evaluation Of In Vitro Diagnostic Medical Devices
EN 18113:2011	Labelling Requirements for IVD Medical Devices

Signed for and on behalf of:

DocuSigned by:
Yuvesh Jain
Signer Name: Yuvesh Jain
Signing Reason: I approve this document
Signing Time: 09-Jan-2024 | 14:05:31 PST
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Yuvesh Jain
RC 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
HistoCore I-Scan Kit	S45.4507
HistoCore PELORIS 3 Barcode Scanner Kit	S45.4508
HistoCore PELORIS 3 Win10/I-Scan Upgrade Kit	B45.5120
HistoCore PELORIS 3 Win10 Upgrade Kit	B45.5121

Revision No.	Date	Summary of Changes
A01	18 Feb 2022	Initial release and date of first compliance with Initial (EU) 2017/746
A02	06 June 2022	Update to add HistoCore I-Scan Kit and HistoCore PELORIS 3 Barcode Scanner kit
A03	21 Apr 2023	Update to include the intended use
A04	22 Aug 2023	Addition of HistoCore PELORIS 3 Win10/I-Scan Upgrade Kit and HistoCore PELORIS 3 Win10 Upgrade Kit
A05	02 Jan 2024	Additional Standards added