

# EC Declaration of Conformity

According to Annex III of the IVD Directive 98/79/EC

**This is to certify that following IVD products:**

Peloris and Peloris II Dual Retort Rapid Tissue Processors and their associated components listed in the attached Device Schedule,

**Classified as:** "all other IVD Medical Devices" according to Annex I rules,

**Manufactured by:** **Leica Biosystems Melbourne Pty Ltd**  
495 Blackburn Road, Mount Waverley, Victoria, Australia, 3149

1. Comply with all essential requirements (Annex I) of the IVD Directive 98/79/EC. This compliance has been properly documented and covers the items listed in Annex I of the IVD Directive.
2. Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:
  - a. Availability of the technical documentation set in Annex III (section 3), allowing the assessment of the conformity of the product with the requirements of the Directive.
  - b. The manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).
  - c. The manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).
3. Leica Biosystems Melbourne has a Quality System in place based on ISO 13485:2003
4. This Declaration of Conformity is signed below, certifying that the requirements of Annex I and Annex III have been met and documented.

**Authorised Representative:** Leica Biosystems Newcastle Ltd  
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Andrew R. Ellis  
Quality Assurance and Regulatory Affairs Manager  
Leica Biosystems Melbourne Pty Ltd

## Device Schedule

The Peloris™ - System includes the following components, accessories and consumables.

Component	Catalogue Number
Peloris Dual Retort Rapid Tissue Processor (AU, NZ, UK, EU)	26.0001.110
Peloris Dual Retort Rapid Tissue Processor (US, Canada)	26.0005.110
Peloris II Dual Retort Rapid Tissue Processor (AU, NZ, UK, EU)	26.0003.110
Peloris II Dual Retort Rapid Tissue Processor (US, Canada)	26.0008.110
Accessories	
Reagent Bottle Labels	S26.6001.110
Reagent Bottle	S26.0802.110
Condensate Bottle	S26.0812.110
Bottle Caps	S26.0301.110
Bottle Connector Sealing Caps	S26.0822.110
Bottle Connector Retaining Cap	S26.0819.110
Bottle Cap Wrench	S26.1910.110
Reagent Fill and Drain Hose	S26.0432.110
Extended Reagent Fill and Drain Hose	S26.0466.110
Wax Drain Hose	S26.1400.110
Wax Scraper	S26.0027.110
Cassette Basket (No Dividers)	S26.0512.110
Cassette Basket Dividers	S26.0516.110
Spaced Basket	S26.0602.110
Spaced Basket Kit	S26.4503
High Capacity Basket Kit	S26.4504
Carbon Filter	S26.0434.110
Touch Screen Protectors	S26.0389.110
Drip Tray	S26.0020.110
Remote Alarm Connector	S26.4098.110
*** End of Schedule ****	