



# EC Declaration of Conformity

We herewith declare, in exclusive responsibility, that the instrument

## Leica CM1950 – Cryostat

was developed, designed and manufactured to conform with the

- Council Directive 73/23/EEC, (Low Voltage),
- Council Directive 89/336/EEC, Appendix I (Electromagnetic Compatibility) and
- European council Directive 98/79/EC (IVD)

including their amendments up to the date mentioned below.

The following harmonized standards were applied:

- **EN 61010-1: 2001**  
Safety requirements for electrical equipment for measurement, control and laboratory use -  
Part 1: General requirements
- **EN 61010-2-101: 2002**  
Safety requirements for electrical equipment for measurement, control and laboratory use -  
Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
- **EN 591: 2001**  
Instruction for use for in vitro diagnostic instruments for professional use
- **EN 61326-1: 2006**  
Electrical equipment for measurement, control and laboratory use - EMC requirements -  
Part 1: General requirements
- **EN 61326-2-6: 2006**  
Electrical equipment for measurement, control and laboratory use - EMC requirements
- **EN 61000-3-2: 2000**  
Electromagnetic compatibility (EMC)  
Part 3-2: Limits - Limits for harmonic current emissions
- **EN 61000-3-3: 1995 + A1: 2001**  
Part 3: Limits -  
Section 3: Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage  
supply systems, for equipment with rated current  $\leq 16$  A per phase  
Electromagnetic compatibility (EMC)
- **EN 418: 1992**  
Emergency stop equipment.  
Principles for design.
- **EN 1037: 1995**  
Safety of machinery.  
Prevention of unexpected start-up.

In addition, the following in-house standards were applied:

- **DIN EN ISO 9001: 2000**  
Quality management system - requirements.

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May 07, 2007

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