



EC Declaration of Conformity

We herewith declare, in exclusive responsibility, that the instrument

Leica ST5020 – Multistainer

was developed, designed and manufactured to conform with the

- Directive 98/79/EC of the European Parliament and of the Council (in-vitro diagnostic medical devices)

The following harmonized standards were applied:

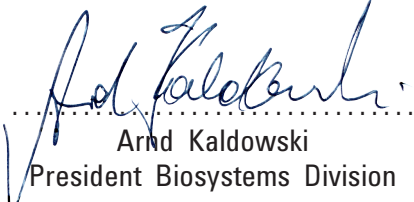
- **EN ISO 14971: 2009**
Medical devices - Application of risk management to medical devices
- **EN 591: 2001**
Instruction for use for in-vitro-diagnostic instruments for professional use
- **EN 980: 2008**
Symbols for use in the labelling of medical devices
- **EN ISO 13485: 2003 + AC: 2007**
Medical devices - Quality management systems - Requirements for regulatory purposes
- **EN 61010-1: 2001 + Corr.: 2002 + Corr.: 2004**
Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: General requirements
- **EN 61010-2-101: 2002**
Safety requirement for electrical equipment for measurement, control and laboratory use Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
- **EN 61326-1: 2006 + Corr.: 2008**
Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements

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

- **DIN EN ISO 9001: 2000**
Quality management systems - Requirements

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