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CE

Declaration of conformity according to the 98/79/EC In-Vitro Diagnostic medical devices Directive (IVD)

DAS srl, manufacturer of the Automated Microplate Analyzer and IFA Slide Processor **"Zenit UP mod. B"**, class of risk In-Vitro Diagnostic Medical Devices, declares that the mentioned instrument complies with the European Directive 98/79/EC (IVD).

The present conformity declaration, as stated in Annex III of the 98/79/EC Directive, is based upon the following requirements:

Quality Management System (ISO 9001:2008): Working Procedures and Instructions for
- Design process control;
- Manufacturing process control;
- Tests and Checks.

System documentation:
- Technical documents;
- Risk analysis;
- User manual;
- Service manual.

The instrument conforms to the following EU directives, including last modifications and related harmonized standard specifications.

- **Directive 2006/95/EC regarding low voltage safety and related standard:**
  - **EN 61010-1(2nd ed.):** Safety for control measurement, and laboratory use equipment
  - **EN 61010-2-081:**Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
  - **EN 61010-2-101:** Particular requirements for in vitro diagnostic (IVD) medical equipment

- **Directive 2004/108/CE - directive regarding electromagnetic compatibility and related standards:**
  - **EN 61326:** Electromagnetic compatibility for control, measurement and laboratory use equipment)
  - **EN 55011:** Industrial, scientific and medical (ISM) radio-frequency Equipment. Electromagnetic disturbance characteristics. Limits and methods of measurement
  - **EN 61000-3-2:** Limits for harmonic current emissions
  - **EN 61000-3-3:** Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems

Palombara Sabina, March 19th, 2014

Mario Orsini
Managing Director

Rev. 5