



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

DAS srl, manufacturer of the ELISA Photometer “**Strip Reader**”, class of risk In-Vitro Diagnostic Medical Devices, declares that the mentioned instrument, beginning from serial number 188, 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 9001:2000): 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:

- 73/23/EC directive regarding low voltage safety
- 89/336/EC directive regarding electromagnetic compatibility

Moreover, below harmonized standard specifications have been applied:

**Risk analysis:**

- EN 14971 (2000) “Application of risk management to medical devices”

**Electrical safety:**

- EN 61010-1 (1997) “Electrical equipment safety requirements for measurement, control and laboratory use – Part 1: general requirements”

**Electromagnetic compatibility:**

- EN 61326-1 (1998) “Electrical equipment for measurement, control and laboratory use – EMC requirements Part 1: general requirements”

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