

**List of applied standards for products of  
DiaSys Diagnostic Systems GmbH  
Alte Strasse 9  
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**Applied Directives:**

**98/79/EC** Directive 98/79/EC on in vitro diagnostic medical devices (IVD Directive).

**For analyser additional**

**2011/65/EU** Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

**Applied Standards**

**General:**

- EN ISO 13485** Medical devices - Quality management systems - Requirements for regulatory purposes
- EN ISO 14971** Medical devices – Application of risk management to medical devices
- EN ISO 15223-1** Medical devices Symbols to be used with medical device labels, labelling and information toBe supplied – Part 1: General requirements
- EN 62366** Medical devices – Application of usability engineering to medical devices

**Reagents**

- EN 13612** Performance evaluation of in vitro diagnostic medical devices
- EN 13641** Elimination or reduction of risk of infection related to in vitro diagnostic reagents
- EN 13975** Sampling procedures used for acceptance testing of in vitro diagnostic medical devices - Statistical aspects
- EN ISO 17511** In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials
- EN ISO 18113-1** In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
- EN ISO 18113-2** In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
- EN ISO 23640** Stability testing of in vitro diagnostic reagent

## **Analyzer**

<b>EN ISO 18113-3</b>	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use
<b>EN 61326-1</b>	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1- General Requirements
<b>EN 61326-2-6</b>	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
<b>EN 61010-1</b>	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
<b>EN 61010-2-101</b>	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
<b>EN 62304</b>	Medical device software - Software life-cycle processes

**Note:** Standards are used in the actual issue or as listed in the latest "List of harmonized standards" according Directive 98/79/EC.

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