

**List of applied standards for products of
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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 to be 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

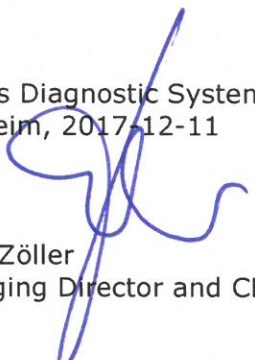
EN ISO 23640 Stability testing of in vitro diagnostic reagent

Analyzer

EN ISO 18113-3	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use
EN 61326-1	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1- General Requirements
EN 61326-2-6	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
EN 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
EN 61010-2-101	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
EN 62304	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.

DiaSys Diagnostic Systems GmbH
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