List of applied standards for products of DiaSys Diagnostic Systems GmbH Alte Strasse 9, 65558 Holzheim

Applied Directives/ Regulations:

For reagents: (EU) 2017/746	REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, *according to Article 55 even in conjugation with Article 110 para. 3 and para. 4.*
For analyser: (EU) 2017/746	REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
2011/65/EU	DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

Applied Standards

General:

EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes

EN ISO 14971:2019 Medical devices - Application of risk management to medical devices

EN ISO 15223-1:2016 Medical devices Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

IEC 62366:2008 Medical devices - Application of usability engineering to medical devices

Reagents:

EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices

EN 13641:2002 Elimination or reduction of risk of infection related to in vitro diagnostic reagents

EN 13975:2003 Sampling procedures used for acceptance testing of in vitro diagnostic medical devices - Statistical aspects

EN ISO 17511:2003 In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials

EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements

EN ISO 18113-2:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use

EN ISO 23640:2015 Stability testing of in vitro diagnostic reagent

EN ISO 15193:2009 In vitro diagnostic medical devices - Measurement of quantities in specimens of biological origin - Requirements for the content and presentation of reference measurement methods

Analyzer:

EN ISO 18113-3:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use

IEC 61326-2-6:2006 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment

IEC 61010-2-101:2002 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

Note: The standards referenced here represent the development status of the product at the time of the conformity assessment. Newer versions of standards are being implemented within the QMS and are only referenced when they have been fully implemented.

Gap analyses have been conducted to ensure that the product complies with the state of the art.

DiaSys Diagnostic Systems GmbH
Holzheim, 2024-03-15

Dr. Jan Gorka
Managing Director and CEO