

CE DECLARATION OF CONFORMITY

Product details:

Product name:	Part No.	Software vers.
AMP Accos 5110 fully automated hematology analyser	HI5110	2.01
IVD-classification acc. to directive 98/79/EC:	other IVD	

We, AMEDA Labordiagnostik GmbH, Krenngasse 12, 8010 Graz, Austria, declare under sole responsibility that the product described above is in compliance with Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in-vitro diagnostic medical devices and that the following harmonized standards have been resp. are applied in development, design and manufacturing.

Safety	EN 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
	EN 61326-2-6:2005	Electrical equipment for measurement, control and laboratory use - EMC requirements – Part 2-6 : particular requirements - In vitro diagnostic (IVD) medical equipment
User Manual	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
Performance	EN 13612:2002	Performance evaluation of IVD medical devices
Symbols	EN 980:2008	Symbols for use in the labelling of medical devices
Risk analysis	EN ISO 14971:2012	Application of risk management to medical devices

The product is CE marked.

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AMEDA Labordiagnostik GmbH
Krenngasse 12 - 8010 Graz - Austria
Tel. +43 - 316 - 69 80 69, Fax ext. - 12

Christine Herfort
CEO

AMEDA Labordiagnostik GmbH