

CE DECLARATION OF CONFORMITY

Product details:

Product name: AMP Hematology Reagents

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 products described above are 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.

Instructions for Use	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
Performance	EN 13612:2002	Performance evaluation of IVD medical devices
Stability	EN 13640:2002	Stability testing of in vitro diagnostic reagents
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
Traceability	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

The products are 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

Product List

Haematology

Part no.	Description	unit
<i>Diluents</i>		
HR3020	AMP HemoDil A 3	20 ltr.
HR0520	AMP HemoDil MEK	20 ltr.
HR5010	AMP HemoDil AS 5	10 ltr.
HR5020	AMP HemoDil AS 5	20 ltr.
HR5320	AMP HemoDil A 5	20 ltr.
<i>Lysing Reagents</i>		
HR3150	AMP HemoLyse A 3	500 mL
HR5100	AMP HemoLyse AS 5	500 mL
HR5101	AMP HemoLyse AS 5	1 ltr.
HR5351	AMP HemoLyse A 5	500 mL
HR5352	AMP HemoLyse A 5 II	500 mL
HR5353	AMP HemoLyse A 5 III	1 ltr.
<i>Cleaning Solution</i>		
HR5120	AMP HemoTerge AS 5	20 ltr.
HR5121	AMP HemoTerge AS 5	10 ltr.
HR2205	AMP HemoTerge MEK	5 ltr.
HR5900	Probe Cleaner	100 mL
HR5901	AMP HemoClean	50 mL
HR5902	AMP HemoClean PB	50 mL
HR5903	AMP HemoClean EZ	50 mL
<i>Other Reagents</i>		
HR5110	AMP HemoSheath AS	10 ltr.