

CE DECLARATION OF CONFORMITY

Product details:

Product name: AMP Hematology Reagents (see annex 1 – 2 pages)

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.



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

Christine Herfort
 CEO

Graz - 28.04.2016

AMEDA Labordiagnostik GmbH

Product List

Haematology

Part no.	Description	unit
Diluents		
HR0220	AMP HemoDil LMG	20 ltr.
HR0520	AMP HemoDil MEK	20 ltr.
HR0620	AMP HemoDil SX	20 ltr.
HR1020	AMP HemoDil A	20 ltr.
HR1120	AMP HemoDil AS	20 ltr.
HR1220	AMP HemoDil X5	20 ltr.
HR5020	AMP HemoDil AS 5	20 ltr.
Lysing Reagents		
HR1050	AMP HemoLyse A	500 mL
HR1101	AMP HemoLyse AS	1 ltr.
HR1201	AMP HemoLyse LMG	1 ltr.
HR1450	AMP HemoLyse MEK 5	500 mL
HR1501	AMP HemoLyse MEK	1 ltr.
HR1550	AMP HemoLyse MEK	500 mL
HR1601	AMP HemoLyse MEK CN free	1 ltr.
HR1650	AMP HemoLyse MEK CN free	500 mL
HR4450	AMP HemoLyse 3SX	500 mL
HR5101	AMP HemoLyse AS 5	1 ltr.
HR6101	AMP HemoLyse X5	1 ltr.
HR6201	AMP HemoLyse Eos	1 ltr.
HR6301	AMP HemoLyse Baso II	1 ltr.
Cleaning Solution		
HR2101	AMP HemoZyme	1 ltr.
HR2201	AMP HemoTerge MEK	1 ltr.
HR2205	AMP HemoTerge MEK	5 ltr.
HR2401	AMP HemoClean X	1 ltr.
HR2500	AMP HemoClair	500 mL
HR2501	AMP HemoClair SX	1 ltr.
HR2551	AMP HemoClair MEK	1 ltr.
HR2600	AMP HemoZyme A	100 mL
HR2601	AMP HemoTerge AS	1 ltr.
HR2605	AMP HemoTerge A	5 ltr.
HR2900	AMP HemoClair AS+	100 mL
HR5120	AMP HemoTerge AS 5	20 ltr.

Product List



Haematology

Part no.	Description	unit
Other Reagents		
HR5110	AMP HemoSheath AS	10 ltr.
HR5205	AMP HemoStain R	50 x 3.7 mL
AMP HemoTrol 16 - 16 Parameter-Kontrolle, 2 ml Röhrchen 16 parameter control, 2 ml vials		
HR9162	AMP HemoTrol 16 - Kit S	1 H, 2 N, 1 L x 2 mL
HR9163	AMP HemoTrol 16 - Kit M	2 H, 4 N, 2 L x 2 mL
HR9164	AMP HemoTrol 16 - Kit L	3 H, 6 N, 3 L x 2 mL
HR9166	AMP HemoTrol 16 Normal	6 N x 2 mL
HR9169	AMP HemoTrol 16 Normal	12 N x 2 mL
AMP HemoTrol 16 - 16 Parameter-Kontrolle, 5 ml Röhrchen mit Septum 16 parameter control, 5 ml vials with piercable cap		
HR9502	AMP HemoTrol 16 - Kit S	1 H, 2 N, 1 L x 5 mL
HR9503	AMP HemoTrol 16 - Kit M	2 H, 4 N, 2 L x 5 mL
HR9504	AMP HemoTrol 16 - Kit L	3 H, 6 N, 3 L x 5 mL
HR9506	AMP HemoTrol 16 Normal	6 N x 5 mL
HR9509	AMP HemoTrol 16 Normal	12 N x 5 mL
AMP HemoTrol 16 - Einzelröhrchen / single vials		
HR9904	AMP HemoTrol 16, single vial - Low	2 mL vial, screw cap
HR9905	AMP HemoTrol 16, single vial - Normal	2 mL vial, screw cap
HR9906	AMP HemoTrol 16, single vial - High	2 mL vial, screw cap
HR9907	AMP HemoTrol 16, single vial - Low	5 mL tube, piercable
HR9908	AMP HemoTrol 16, single vial - Normal	5 mL tube, piercable
HR9909	AMP HemoTrol 16, single vial - High	5 mL tube, piercable
AMP HemoTrol 5D		
HR9352	AMP HemoTrol 5D - Kit S	1 H, 2 N, 1 L x 3 mL
HR9353	AMP HemoTrol 5D - Kit M	2 H, 4 N, 2 L x 3 mL
HR9354	AMP HemoTrol 5D - Kit L	3 H, 6 N, 3 L x 3 mL
HR9355	AMP HemoTrol 5D - Kit IV	4 H, 4 N, 4 L x 3 mL
AMP HemoCal		
HR9800	AMP HemoCal	1 x 3 mL