

Merck KGaA · Frankfurter Straße 250 · 64293 Darmstadt

## Self-Certification of In Vitro Diagnostic Medical Devices

in accordance with the  
DIRECTIVE 98/79/EC OF THE EUROPEAN  
PARLIAMENT AND OF THE COUNCIL  
of 27 October 1998  
on in vitro diagnostic medical devices

Datum 12.04.2012  
Bereich/Abt. MM-LE  
Zuständig Dr. Andreas Rauh  
Tel. +49 6151 72-8192  
Fax +49 6151 72-918192  
E-Mail andreas.rauh@merckgroup.com

To whom it may concern

## EC Declaration of conformity

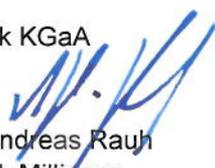
For each of the Merck products listed in the enclosure, the assessment of conformity has been successfully performed and documented in accordance with the provisions of Article 9, and Annexes I and III of the "Directive 98/79/EC". All supporting documentation is retained in the premises of the manufacturer.

For the products listed in the enclosure, DQS GmbH has certified that Merck KGaA has implemented and maintains a Quality Management System that fulfils the standard of DIN EN ISO 13485: 2003 + AC: 2009 (certificate registration no. 005356 MP29)

Classification: The products listed in the enclosure are classified as being "in vitro diagnostic medical devices" according to Article 1 of the "Directive 98/79/EC". The products are not subject to Annex II of the Directive 98/79/EC, they are not for use by lay persons and they are no self-test devices.

Note: This EC Declaration of Conformity replaces the one for Merck KGaA's In Vitro Diagnostic Medical Devices of June 01, 2011

Merck KGaA

ppa.   
Dr. Andreas Rauh  
Merck Millipore  
Lab Essentials

i. A.   
Dr. Klaus Büscher  
Merck Millipore  
Quality Assurance Site Darmstadt

Merck Millipore ist eine Sparte von 

Merck KGaA

Frankfurter Straße 250 · 64293 Darmstadt  
Postfach · 64271 Darmstadt  
Tel. +49 6151 72-0  
Fax +49 6151 72-2000  
www.merck.de

Kommanditgesellschaft auf Aktien  
Handelsregister AG Darmstadt HRB 6164  
Sitz der Gesellschaft: Darmstadt  
Vorsitzender des Aufsichtsrats:  
Rolf Krebs

Geschäftsleitung  
und persönlich haftende Gesellschafter:  
Karl-Ludwig Kley (Vorsitzender),  
Kai Beckmann, Stefan Oschmann,  
Bernd Reckmann, Matthias Zachert

## List of CE-certified Microscopy/Cell Diagnostic Products of Merck KGaA

Art.-No.	Description
<b>Bacteriology</b>	
100327	HYDROCHLORIC ACID IN ETHANOL FOR MICROSCOPY
100497	TB-COLOR MODIFIED STAINING KIT FOR THE DETECTION OF MYCOBACTERIA (AFB) BY HOT STAINING METHOD
100567	LUGOL'S SOLUTION STABILIZED WITH PVP FOR THE GRAM STAINING
101287	LOEFFLER'S METHYLENE BLUE SOLUTION FOR MICROSCOPY
101301	AURAMINE (C.I. 41000) FOR MICROSCOPY
101374	BRILLIANT GREEN (HYDROGEN SULFATE) (C.I. 42040) FOR MICROSCOPY CERTISTAIN®
101398	MALACHITE GREEN OXALATE (C.I. 42000) FOR MICROSCOPY AND FOR MICROBIOLOGY
101597	TB-FLUOR PHENOL-FREE STAINING KIT FOR THE ACID-FAST SMEAR EXAMINATION WITH FLUORESCENCE MICROSCOPY
101603	GRAM-COLOR MODIFIED (PHENOL-FREE) STAINING KIT FOR GRAM STAINING METHOD ON BACTERIOLOGICAL SMEARS
105226	NEW FUCHSIN (C.I. 42520) FOR MICROSCOPY CERTISTAIN®
107599	RHODAMINE B (C.I. 45170) FOR MICROSCOPY
108000	SPUTOFLUOL FOR MICROBIOLOGY AND MICROSCOPY
108512	TB-COLOR CARBOL FUCHSIN SOLUTION FOR THE MICROSCOPIC COLD STAINING OF MYCOBACTERIA
109093	TB-FLUOR STAINING KIT FOR FLUORESCENCE-MICROSCOPIC DETECTION OF ACID FAST BACTERIA
109215	ZIEHL-NEELSEN CARBOL-FUCHSIN SOLUTION FOR MICROSCOPY
109217	GRAM'S SAFRANINE SOLUTION FOR THE GRAM STAINING METHOD
109218	GRAM'S CRYSTAL VIOLET SOLUTION FOR THE GRAM STAINING METHOD
109261	LUGOL'S SOLUTION (DILUTED IODINE-POTASSIUM IODIDE SOLUTION) FOR THE GRAM STAINING METHOD
110218	GRAM'S DECOLORIZING SOLUTION FOR THE GRAM STAINING METHOD
110630	TB-COLOR MALACHITE GREEN (OXALATE) SOLUTION FOR THE MICROSCOPIC INVESTIGATION OF MYCOBACTERIA
111885	GRAM-COLOR STAIN SET FOR THE GRAM STAINING METHOD
113741	LACTOPHENOL BLUE SOLUTION FOR STAINING FUNGI
115924	NIGROSINE (C.I. 50420) WATER-SOLUBLE FOR MICROSCOPY CERTISTAIN®
115931	ACRIDINE ORANGE ZINC CHLORIDE DOUBLE SALT (C.I.46005) FOR MICROSCOPY CERTISTAIN®
115937	FUCHSIN (C.I. 42510) FOR MICROSCOPY CERTISTAIN®
115940	CRYSTAL VIOLET (C.I. 42555) FOR MICROSCOPY CERTISTAIN®

115942	MALACHITE GREEN (OXALATE) (C.I. 42000) FOR MICROSCOPY CERTISTAIN <sup>®</sup>
115948	SAFRANINE O (C.I. 50240) FOR MICROSCOPY CERTISTAIN <sup>®</sup>
116450	TB-COLOR STAINING KIT FOR THE MICROSCOPIC INVESTIGATION OF MYCOBACTERIA (COLD STAINING)
<b>Haematology</b>	
101324	JANUS GREEN (C.I.11050) FOR MICROSCOPY
101350	LEISHMAN'S EOSINE-METHYLENE BLUE FOR MICROSCOPY
101352	MAY-GRUENWALD'S EOSINE METHYLENE BLUE FOR MICROSCOPY
101368	BRILLIANT CRESYL BLUE ZINC CHLORIDE DOUBLE SALT FOR MIROSCOPY CERTISTAIN <sup>®</sup>
101383	WRIGHT'S EOSIN METHYLENE BLUE SOLUTION FOR MICROSCOPY
101384	BRILLIANT CRESYL BLUE SOLUTION FOR THE STAINING OF RETICULOCYTES AND TRICHOMONADS FOR MICROSCOPY
101424	MAY-GRUENWALD'S EOSINE-METHYLENE BLUE SOLUTION MODIFIED FOR MICROSCOPY
105387	LEISHMAN'S EOSIN METHYLENE BLUE SOLUTION MODIFIED FOR MICROSCOPY
109203	GIEMSA'S AZUR-EOSIN-METHYLENE BLUE FOR MICROSCOPY
109204	GIEMSA'S AZUR EOSIN METHYLENE BLUE SOLUTION FOR MICROSCOPY
109211	AZURE II (C.I. 52010/52015) FOR MICROSCOPY
109277	TUERK'S SOLUTION FOR LEUCOCYTE COUNTING
109278	WRIGHT'S EOSIN METHYLENE BLUE FOR MICROSCOPY
109468	BUFFER TABLETS PH 7.2 FOR PREPARING BUFFER SOLUTION ACC. TO WEISE FOR STAINING OF BLOOD SMEARS
111373	BUFFER TABLETS PH 6.4 FOR PREPARING BUFFER SOLUTION ACC. TO WEISE FOR THE STAINING OF BLOOD SMEARS
111374	BUFFER TABLETS PH 6.8 FOR PREPARING BUFFER SOLUTION ACC. TO WEISE FOR THE STAINING OF BLOOD SMEARS
111661	HEMACOLOR <sup>®</sup> RAPID STAINING OF BLOOD SMEAR STAINING SET FOR MICROSCOPY
111674	HEMACOLOR <sup>®</sup> RAPID STAINING OF BLOOD SMEAR STAINING SET FOR MICROSCOPY
111955	HEMACOLOR <sup>®</sup> RAPID STAINING OF BLOOD SMEAR SOLUTION 1 FIXING SOLUTION
111956	HEMACOLOR <sup>®</sup> RAPID STAINING OF BLOOD SMEAR SOLUTION 2 COLOUR REAGENT RED
111957	HEMACOLOR <sup>®</sup> RAPID STAINING OF BLOOD SMEAR SOLUTION 3 COLOUR REAGENT BLUE
112084	HEMATOGNOST <sup>®</sup> FE STAINING KIT FOR THE DETECTION OF FREE IONIC IRON (FE <sup>3+</sup> ) IN CELLS
112327	LEUCOGNOST <sup>®</sup> MIXTURE OF FIXATIVES FIXATIVE FOR ENZYME CYTOCHEMISTRY
115213	AUTO-HEMACOLOR <sup>®</sup> STAINING SET FOR AUTOMATIC BLOOD SMEAR STAINING WITH THE HEMA-TEK SLIDE STAINER
115332	SANGODIFF <sup>®</sup> G STAINING FOILS FOR MANUAL STAINING OF BLOOD SMEARS
115943	METHYLENE BLUE (C.I. 52015) FOR MICROSCOPY CERTISTAIN <sup>®</sup>
116198	LEUCOGNOST <sup>®</sup> NASDCL DETECTION OF NAPHTHOL AS-D CHLOROACETATE ESTERASE IN GRANULOCYTES

116300	LEUCOGNOST® ALPA DETECTION OF THE ALKALINE LEUKOCYTE PHOSPHATASE ACTIVITY IN LEUKOCYTES
116301	LEUCOGNOST® EST DETECTION OF THE ALPHA NAPHTHYL ACETATE ESTERASE REACTION IN LEUKOCYTES
116302	LEUCOGNOST® PAS DETECTION OF THE PERIODIC ACID-SCHIFF REACTION IN LEUKOCYTES
116303	LEUCOGNOST® POX DETECTION OF THE PEROXIDASE REACTION IN LEUKOCYTES
116304	LEUCOGNOST® SP DETECTION OF THE ACID PHOSPHATASE REACTION IN LEUKOCYTES
116305	LEUCOGNOST® BASIC KIT FOR DIAGNOSIS OF LEUKEMIA
<b>Cytology</b>	
104302	HEMATOXYLIN CRYST. (C.I. 75290) FOR MICROSCOPY
105175	HEMATOXYLIN SOLUTION MODIFIED ACC. TO GILL II FOR MICROSCOPY
106887	PAPANICOLAOU'S SOLUTION 2B ORANGE II SOLUTION FOR CYTOLOGICAL CANCER AND CYCLE DIAGNOSIS
106888	PAPANICOLAOU'S SOLUTION 2A ORANGE G SOLUTION (OG 6) FOR CYTOLOGICAL CANCER AND CYCLE DIAGNOSIS
109253	PAPANICOLAOU'S SOLUTION 1A HARRIS' HEMATOXYLIN SOLUTION FOR CYTOLOGICAL CANCER AND CYCLE DIAGNOSIS
109254	PAPANICOLAOU'S SOLUTION 1B HEMATOXYLIN SOLUTION S FOR CYTOLOGICAL CANCER AND CYCLE DIAGNOSIS
109269	PAPANICOLAOU'S SOLUTION 3D POLYCHROMATIC SOLUTION EA 65 FOR CYTOLOGICAL CANCER AND CYCLE DIAGNOSIS
109270	PAPANICOLAOU'S SOLUTION 3C POLYCHROMATIC SOLUTION EA 65 FOR CYTOLOGICAL CANCER AND CYCLE DIAGNOSIS
109271	PAPANICOLAOU'S SOLUTION 3A POLYCHROMATIC SOLUTION EA 31 FOR CYTOLOGICAL CANCER AND CYCLE DIAGNOSIS
109272	PAPANICOLAOU'S SOLUTION 3B POLYCHROMATIC SOLUTION EA 50 FOR CYTOLOGICAL CANCER AND CYCLE DIAGNOSIS
109275	SHORR STAINING SOLUTION FOR HORMONAL CYTODIAGNOSIS
111487	HEMATEIN (C.I. 75290) FOR MICROSCOPY
115355	CYTOLOGICAL STANDARD STAIN ACC. TO SZCZEPANIK FOR MICROSCOPY CYTOCOLOR®
115925	ORANGE G (C.I. 16230) FOR MICROSCOPY CERTISTAIN®
115938	HEMATOXYLIN MONOHYDRATE (C.I.75290) FOR MICROSCOPY CERTISTAIN®
<b>Histology</b>	
100121	NUCLEAR FAST RED –ALUMINUM SULFATE SOLUTION 0.1%
100199	VAN GIESON'S PICROFUCHSDIN SOLUTION
100211	CARMINIC ACID (C.I. 75470) GR FOR ANALYSIS AND FOR MICROSCOPY
100251	RETICULIN SILVER PLATING KIT ACC. TO GORDON & SWEETS
100361	ISOSLIDE® RETICULIN CONTROL SLIDES WITH REFERENCE TISSUE FOR THE DETECTION

	OF RETICULAR FIBERS IN HISTOLOGY
100362	SILVER STAINING KIT ACC: TO VON KOSSA FOR MICROSCOPY
100485	MASSON-GOLDNER STAINING KIT FOR THE TRICHROMIC VISUALISATION OF CONNECTIVE TISSUE
100820	METHENAMINE SILVER PLATING KIT ACC. TO GOMORI FOR MICROSCOPY
101167	AMIDO BLACK 10 B (C.I. 20470) FOR MICROSCOPY AND FOR ELECTROPHORESIS
101376	NEUTRAL RED (C.I. 50040) FOR MICROSCOPY CERTISTAIN®
101641	CONGO RED STAINING KIT FOR DETECTION OF AMYLOID ACC. TO HIGHMAN
101646	PAS STAINING KIT FOR DETECTION OF ALDEHYDE AND MUKO SUBSTANCES
101647	ALCIAN BLUE SOLUTION FOR MICROSCOPY
102414	WARTHIN-STARRY SILVER PLATING KIT MODIFIED
102439	EOSIN Y-SOLUTION 0.5% ALCOHOLIC FOR MICROSCOPY
104022	FAST GREEN FCF (C.I. 42053) FOR MICROSCOPY CERTISTAIN®
104741	INDIGO CARMINE (C.I. 73015) FOR MICROSCOPY CERTISTAIN®
105174	HEMATOXYLIN SOLUTION MODIFIED ACC. TO GILL III FOR MICROSCOPY
105230	OIL RED O (C.I. 26125) FOR MICROSCOPY CERTISTAIN®
105231	FUCHSIN ACID (C.I. 42685) FOR MICROSCOPY CERTISTAIN®
105234	ALCIAN BLUE 8 GX (C.I.74240) FOR MICROSCOPY CERTISTAIN®
105235	CRESYL VIOLET (ACETATE) FOR MICROSCOPY CERTISTAIN®
107100	ORCEIN FOR MICROSCOPY CERTISTAIN®
107509	PARAROSANILINE (CHLORIDE) (C.I. 42500) FOR MICROSCOPY CERTISTAIN®
107518	PYRONINE G (C.I. 45005) FOR MICROSCOPY CERTISTAIN®
107907	DNA STAINING KIT ACCORDING TO FEULGEN
108103	TETRAZOLIUM BLUE FOR MICROSCOPY
109033	SCHIFF'S REAGENT FOR ELECTROPHORESIS AND MICROSCOPY
109249	MAYER'S HEMALUM SOLUTION FOR MICROSCOPY
109844	EOSIN Y-SOLUTION 0.5% AQUEOUS FOR MICROSCOPY
111732	TRYPAN BLUE (C.I. 23850) FOR MICROSCOPY
115926	PHLOXIN B (C.I. 45410) FOR MICROSCOPY CERTISTAIN®
115927	PONCEAU S (C.I. 27195) FOR MICROSCOPY CERTISTAIN®
115929	THIONINE (ACETATE) (C.I. 52000) FOR MICROSCOPY CERTISTAIN®
115930	TOLUIDINE BLUE O (C.I.52040) FOR MICROSCOPY CERTISTAIN®
115933	CARMINE (C.I. 75470) (CALCIUM-ALUMINIUM LACQUER OF CARMINIC ACID) FOR MICROSCOPY CERTISTAIN®
115934	EOSIN B (C.I. 45400) FOR MICROSCOPY CERTISTAIN®
115935	EOSIN Y (YELLOWISH)(C.I. 45380) FOR MICROSCOPY CERTISTAIN®
115936	ERYTHROSINE B (C.I. 45430) FOR MICROSCOPY CERTISTAIN®
115939	NUCLEAR FAST RED (C.I. 60760) FOR MICROSCOPY CERTISTAIN®
115941	LIGHT GREEN SF YELLOWISH (C.I. 42095) FOR MICROSCOPY CERTISTAIN®
115944	METHYL GREEN ZINC CHLORIDE DOUBLE SALT (C.I. 42590) FOR MICROSCOPY

	CERTISTAIN®
115945	METHYL VIOLET (C.I. 42535) FOR MICROSCOPY CERTISTAIN®
115946	NILE BLUE (HYDROGEN SULFATE) (C.I. 51180) FOR MICROSCOPY CERTISTAIN®
115973	WEIGERT'S IRON HEMATOXYLIN KIT FOR NUCLEAR STAINING IN HISTOLOGY
115974	ELASTICA VAN GIESON STAINING KIT FOR CONNECTIVE TISSUE
116316	METHYL BLUE (C.I. 42780) FOR MICROSCOPY
124546	FLUORESCEIN-5-ISOTHIOCYANATE FOR BIOCHEMISTRY AND FOR FLUORESCENCE MICROSCOPY
124653	4',6-DIAMIDINO-2-PHENYLINDOLE DIHYDROCHLORIDE (DAPI) FOR MICROSCOPY
124823	NITRO BLUE TETRAZOLIUM CHLORIDE (NBT) FOR MICROSCOPY
<b>Miscellaneous reagents:</b>	
fixing reagents, mounting media, embedding media, immuno-histological kits, other histo-/cytological reagents	
100496	FORMALDEHYDE SOLUTION 4% BUFFERED (pH 6.9) FOR HISTOLOGY
101691	CANADA BALSAM FOR MICROSCOPY
101728	OSTEOSOFT® MILD DECALCIFER-SOLUTION FOR HISTOLOGY
101736	OSTEOMOLL® RAPID DECALCIFER-SOLUTION FOR HISTOLOGY
102924	DAB-BUFFER TABLETS FOR IMMUNOHISTOCHEMISTRY
103973	MERCKOGLAS® LIQUID COVER GLASS FOR MICROSCOPY
103981	MERCKOFIX® SPRAY FIXATIVE FOR CYTODIAGNOSIS
103999	FORMALDEHYDE SOLUTION MIN. 37% FREE FROM ACID STABILIZED WITH ABOUT 10% METHANOL AND CALCIUM CARBONATE FOR HISTOLOGY
104095	GLYCEROL FOR FLUORESCENCE MICROSCOPY
104239	GLUTARDIALDEHYDE SOLUTION 25% FOR ELECTRON MICROSCOPY
104699	IMMERSION OIL FOR MICROSCOPY
106965	OIL OF CEDAR WOOD FOR MICROSCOPY
107164	PARAFFIN PASTILLES SOLIDIFICATION POINT ABOUT 56-58 GRAD C FOR HISTOLOGY
107960	ENTELLAN® RAPID MOUNTING MEDIUM FOR MICROSCOPY
107961	ENTELLAN® NEW RAPID MOUNTING MEDIUM FOR MICROSCOPY
108562	AQUATEX® (AQUEOUS MOUNTING AGENT) FOR MICROSCOPY
109016	NEO-MOUNT® ANHYDROUS MOUNTING MEDIUM FOR MICROSCOPY
109242	KAISER'S GLYCEROL GELATIN FOR MICROSCOPY
109266	OSMIC ACID SOLUTION 2% FOR ELECTRON MICROSCOPY
109843	NEO-CLEAR® (XYLENE SUBSTITUTE) FOR MICROSCOPY
111609	HISTOSEC® PASTILLES SOLIDIFICATION POINT 56-58 GRAD C EMBEDDING AGENT FOR HISTOLOGY
112179	GLUTARDIALDEHYDE SOLUTION 25% FOR ELECTRON MICROSCOPY, ACC. TO P.J. ANDERSON
115161	HISTOSEC® PASTILLES (WITHOUT DMSO) SOLIDIFICATION POINT 56-58 GRAD C EMBEDDING AGENT FOR HISTOLOGY
115577	IMMERSION OIL ACC. TO DIN ISO 8036-1 FOR MICROSCOPY

124505	OSMIUM(VIII) OXIDE FOR MICROSCOPY
	<b>Clinical Chemistry</b>
1095841111	pH-INDICATOR STRIPS NON-BLEEDING pH 2.0 – 9.0