

EC Declaration of Conformity

According to article 9 of Directive 98/79/EC
on In vitro Diagnostic Medical Devices

Manufacturer

Zytomed Systems GmbH
Anhaltinerstraße 16
14163 Berlin
Germany

Zytomed Systems GmbH hereby declares, that products listed below are in conformity with Annex I (Essential Requirements) and Annex III (EC Declaration of Conformity) of Directive

98/79/EC

Zytomed Systems GmbH

Berlin, 19.12.16
Place, Date

T. Dittmer
Thomas Dittmer (CEO)

Products

Primary Antibodies

Product Name

Catalogue numbers

Actin alpha (Smooth Muscle)	MSG030, MSK030, MSK030-05, BMS001
ALK/p80	MSK096-05
BCL-2	RBG016, RBK016, RBK016-05, BMS021
C3d Complement factor	RBG034, RBK034-05
C4d Complement factor	RBG061, RBK061-05
CA19-9	MSG094, MSK094-05
Cadherin 17	MSG105, MSK105-05
Caldesmon	RBG040, RBK040-05
Calponin-1	RBG041, RBK041-05
Calretinin	RBG003, RBK003, RBK003-05, BRB022
CD1a	RBG045, RBK045-05
CD3 (T-Cell)	RBG015, RBK015, RBK015-05, BBR041
CD4 (T-Cell helper/inducer)	BRB042
CD8 (T-Cell cytotoxic/suppressor)	MSG011, MSK011, MSK011-05, BRB036
CD10 (CALLA)	MSG070, MSK070, MSK070-05, BMS043
CD11c	MSG093, MSK093-05
CD14	RBK033-05
CD15	MSG005, MSK005, MSK005-05
CD20	MSG008, MSK008, MSK008-05, BMS003
CD21	RBG036, RBK036-05
CD30	MSG061, MSK061, MSK061-05
CD31	BMS044
CD34	BMS045
CD43 (Leukosialin, Sialophorin)	MSG010, MSK010, MSK010-05
CD45 (LCA)	MSG054, MSK054, MSK054-05, BMS046
CD56 (N-CAM, NKH1, SCLC)	RBG050, RBK050, RBK050-05, BRB039
CD61	MSG086, MSK086, MSK086-05
CD68 (Macrosialin)	MSG055, MSK055, MSK055-05
CD79a (B-Cell)	MSG036, MSK036, MSK036-05, BMS005
CD138 (Syndecan-1)	MSG063, MSK063, MSK063-05
CDX2	RBG019, RBK019, RBK019-05, BRB028
CEA (Carcinoembryonic Antigen)	MSG022, MSK022, MSK022-05, BMS029
Chromogranin A	MSG062, MSK062, MSK062-05, BMS018
Cytokeratin (HMW)	MSG027, MSK027, MSK027-05, BMS015
Cytokeratin (pan)	MSG019, MSK019, MSK019-05, BMS006
Cytokeratin 19	MSG017, MSK017, MSK017-05
Cytokeratin 20	BMS037
Cytokeratin 5 & 6	MSG034, MSK034, MSK034-05, BMS017
Cytokeratin 5 & 14	MSG106, MSK106, MSK106-05, BMS023,
Cytokeratin 7	MSG032, MSK032, MSK032-05, BMS030
Cytokeratin Pan Plus	MSG098, MSK098-05
Desmin	MSG053, MSK053, MSK053-05, BMS007
E-Cadherin	MSG033, MSK033, MSK033-05
E-Cadherin	RBG043, RBK043, RBK043-05, BRB047
EMA	MSG059, MSK059, MSK059-05
Epithelial Specific Antigen (Ep-CAM)	MSG066, MSK066, MSK066-05, BMS048
ERG	MSG090, MSK090-05
Estrogen Receptor	MSG001, MSK001, MSK001-05, BMS008
Estrogen Receptor	BRB053
Factor XIIIa (Fibrinolygase)	RBG044, RBK044, RBK044-05
GATA-3	MSG100, MSK100-05, BMS054
GCDFP-15	RBG032, RBK032-05
GFAP (Glial Fibrillary Acidic Protein)	RBG037, RBK037, RBK037-05
GLUT 1	BRB049
Glypican-3	MSG067, MSK067-05

Helicobacter pylori	RBG012, RBK012, RBK012-05, BRB032
Hemoglobin A	RBK035-05
HER2 (Extracellular domain)	MSG003, MSK003, MSK003-05
HER2 (Intracellular domain)	MSG044, MSK044, MSK044-05, BMS014
HER2easy Kit	ZUC063
HGAL	MSG088, MSK088-05
HHV-8	MSG085, MSK085-05
IgG4, Human	MSG084, MSK084-05
INI-1	MSK078-05
Ki-67	RBG027, RBK027, RBK027-05, BRB040
Ki-67	MSG018, MSK018, MSK018-05, BMS009
Ksp-Cadherin	MSG068, MSK068, MSK068-05
Langerin	MSG103, MSK103
Mammaglobin	RBG022, RBK022-05
MART-1 (Melan-A)	MSG056, MSK056, MSK056-05
Melanoma (HMB45)	MSG007, MSK007, MSK007-05, BMS010
Melanoma Assoc. Antigen KBA.62	MSG080, MSK080-05
Melanoma Assoc. Antigen PNL2	MSG082, MSK082-05
MLH-1 (Antibody Diluent B included)	MSK045-05, BMS033
MSH2 (MutS homologue 2)	MSG031, MSK031-05, BMS034
Myosin SM Heavy Chain	MSG081, MSK081-05
Napsin A	RBG059, RBK059-05
Neurofilament L + H	MSG060, MSK060, MSK060-05
NKX3-1	RBG062, RBK062-05
Oct-2	MSG073, MSK073-05
p40	MSG097, MSK097, MSK097-05, BMS050
p40	RBG054, RBK054-05
p53	MSG020, MSK020, MSK020-05
Parathyroid Hormone (PTH)	MSG072, MSK072, MSK072-05
PAX-5	BRB027
PAX-8	RBG047, RBK047-05
PAX-8	MSG107, MSK107-05
PD-L1	RBG063, RBK063-05
PMS2	RBG048
Podoplanin (Lymphatic endothelium)	MSG057, MSK057, MSK057-05
Progesterone Receptor SP42	RBG020, RBK020, RBK020-05, BRB038
Progesterone Receptor PR-1	MSG002, MSK002, MSK002-05
Protein Gene Product 9.5	RBG064, RBK064-05
PU.1	RBG042, RBK042-05
S100	MSG050, MSK050, MSK050-05, BMS013
S100P	MSG089, MSK089-05
SOX-10	RBG057, RBK057-05
SOX-11	MSG095, MSK095-05
Synaptophysin	RBG011, RBK011, RBK011-05
T-bet	RBG049, RBK049-05
TdT	RBG052, RBK052, RBK052-05
Thyroglobulin	MSG039, MSK039, MSK039-05
TTF-1 (Thyroid Transcription Factor 1)	MSG004, MSK004, MSK004-05, BMS016
Uroplakin II	MSG102, MSK102-05
Vimentin	MSG023, MSK023, MSK023-05, BMS012

Detection Kits

Product Name

ZytoChem Plus (AP) Polymer Kit
 ZytoChem Plus (HRP) Polymer Kit
 ZytoChem Plus (HRP) One-Step Polymer
 anti-Mouse/Rabbit/Rat
 ZytoChem Plus (HRP) Polymer anti-Rabbit

Catalogue numbers

POLAP-006, POLAP-100
 POLHRP-006, POLHRP-100
 ZUC053-006, ZUC053-100
 ZUC032-006, ZUC032-100

ZytoChem Plus (HRP) Polymer anti-Mouse	ZUC050-006, ZUC050-100
ZytoChem Plus (AP) Polymer anti-Mouse	ZUC077-006, ZUC077-100
ZytoChem Plus (AP) Polymer anti-Rabbit	ZUC031-006
ZytoChem Fast (AP) One-Step Polymer anti-Mouse/Rabbit/Rat	
ZytoChemPlus (AP) Broad Spectrum (Fast Red) Kit	ZUC068-006, ZUC068-100
ZytoChemPlus (AP) Broad Spectrum Kit	AP008RED
ZytoChemPlus (HRP) Broad Spectrum (AEC) Kit	AP060, AP125, AP500
ZytoChemPlus (HRP) Broad Spectrum (DAB) Kit	HRP008AEC
ZytoChemPlus (HRP) Broad Spectrum Bulk Kit	HRP008DAB
ZytoChemPlus (AP) Anti-Mouse (Fast Red) Kit	HRP060, HRP125, HRP500
ZytoChemPlus (AP) Anti-Mouse Bulk Kit	AP008RED-MS
ZytoChemPlus (HRP) Anti-Mouse (AEC) Kit	AP060-MS, AP125-MS, AP500-MS
ZytoChemPlus (HRP) Anti-Mouse (DAB) Kit	HRP008AEC-MS
ZytoChemPlus (HRP) Anti-Mouse Bulk Kit	HRP008DAB-MS
ZytoChemPlus (AP) Anti-Rabbit (Fast Red) Kit	HRP060-MS, HRP125-MS, HRP500-MS
ZytoChemPlus (AP) Anti-Rabbit Bulk Kit	AP008RED-RB
ZytoChemPlus (HRP) Anti-Rabbit (AEC) Kit	AP060-RB, AP125-RB, AP500-RB
ZytoChemPlus (HRP) Anti-Rabbit (DAB) Kit	HRP008AEC-RB
ZytoChemPlus (HRP) Anti-Rabbit Bulk Kit	HRP008DAB-RB
ZytoChem (AP) Broad Spectrum (Fast Red) Kit	HRP060-RB, HRP125-RB, HRP500-RB
ZytoChem (AP) Broad Spectrum Bulk Kit	AP-S-008RED
ZytoChem (HRP) Broad Spectrum (AEC) Kit	AP-S-125, AP-S-500
ZytoChem (HRP) Broad Spectrum (DAB) Kit	HRP-S-008AEC
ZytoChem (HRP) Broad Spectrum Bulk Kit	HRP-S-008DAB
	HRP-S-125, HRP-S-500

Chromogens and Accessories

Product Name

Catalogue numbers

AEC Single Solution	ZUC037-008, ZUC037-100
AEC Substrate Kit	ZUC042-050, ZUC042-500
Antibody Diluent	ZUC025-100, ZUC042-500
Antibody Diluent B	ZUC051-025, ZUC051-100
Blockingsolution - SuperBlock	ZUC007-100
DAB High contrast Kit	DAB500plus, DAB5000plus
DAB Substrate Kit (Brown)	DAB057, DAB530
DAB Substrate Buffer	ZUC018-500
Fast-Red Substrate Pack	RED055, RED125, RED500
Pepsin	ZUC038-060
Permanent AP-Red Kit	ZUC001-125, ZUC001-500
Peroxid-Block	ZUC019-008, ZUC019-100, ZUC019-500
ZytoChem Plus Biotinylated Sec. Antibody	ZUC008-008, ZUC008-125
Zytomed Systems HIER Citrate Buffer pH 6.0 (10 X)	ZUC028-100, ZUC028-500
Zytomed Systems HIER Tris-EDTA Buffer pH 8.0 (10 X)	ZUC040-100, ZUC040-500
Zytomed Systems HIER Tris-EDTA Buffer pH 9.0 (10 X)	ZUC029-100, ZUC029-500
Zytomed Systems Wash Buffer (20 X)	ZUC020-500, ZUC020-2500