



# BD Declaration of Conformity

<b>Manufacturer:</b>	Becton, Dickinson and Company BD Biosciences 2350 Qume Drive San Jose, CA 95131, USA Tel: 877.232.8995 / Fax: 408.954.2347
<b>Authorized Representative:</b>	Benex Limited Pottery Road, Dun Laoghaire Co. Dublin, Ireland Tel: +353.1.202.5222 / Fax: +353.1.202.5388
<b>Conformity assessment procedure:</b>	Annex III of the IVD Directive 98/79/EC.
<b>Product:</b>	345784 - CD14 FITC (MIP9) 333951 - CD14 APC-Cy7 (MIP9) 345787 - CD14 APC (MIP9) 345786 - CD14 PerCP (MIP9) 345785 - CD14 PE (MIP9)
<p><b>We hereby declare that the above mentioned product(s) manufactured after 2017/10/01 complies with the above listed Directive(s) and its relevant transposition into national laws of the member states into which we place the devices.</b></p>	
<b>Signed In San Jose:</b>	2017/10/01
<b>Name and Authority:</b>	Paul Arrendell, WW VP Quality Management
<b>Signature:</b>	

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<b>Conformity assessment procedure:</b>	Annex III of the IVD Directive 98/79/EC.
<b>Product:</b>	332778 - CD15 (MMA) FITC -
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<b>Conformity assessment procedure:</b>	Annex III of the IVD Directive 98/79/EC.
<b>Product:</b>	335035 - CD16 (NKP15) FITC -
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<b>Conformity assessment procedure:</b>	Annex III of the IVD Directive 98/79/EC.
<b>Product:</b>	338440 - CD16 (3G8) PerCP-Cy5.5 -
<p><b>We hereby declare that the above mentioned product(s) manufactured after 2017/10/01 complies with the above listed Directive(s) and its relevant transposition into national laws of the member states into which we place the devices.</b></p>	
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<b>Conformity assessment procedure:</b>	Annex III of the IVD Directive 98/79/EC.
<b>Product:</b>	332779 - CD16 (B73.1) PE 335823 - CD16 (B73.1) PE-Cy (TM) 7
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<b>Conformity assessment procedure:</b>	Annex III of the IVD Directive 98/79/EC.
<b>Product:</b>	345776 - CD19 (4G7) FITC 345778 - CD19 (4G7) PerCP 345777 - CD19 (4G7) PE
<p><b>We hereby declare that the above mentioned product(s) manufactured after 2017/10/01 complies with the above listed Directive(s) and its relevant transposition into national laws of the member states into which we place the devices.</b></p>	
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<b>Conformity assessment procedure:</b>	Annex III of the IVD Directive 98/79/EC.
<b>Product:</b>	345788 - CD19 (SJ25C1) FITC 345791 - CD19 (SJ25C1) APC 348814 - CD19 (SJ25C1) APC-Cy(TM)7 345790 - CD19 (SJ25C1) PerCP 332780 - CD19 (SJ25C1) PerCP-Cy(TM)5.5 345789 - CD19 (SJ25C1) PE 341113 - CD19 (SJ25C1) PE-Cy(TM)7
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<b>Conformity assessment procedure:</b>	Annex III of the IVD Directive 98/79/EC.
<b>Product:</b>	345792 - CD20 (L27) FITC 340908 - CD20 (L27) APC 335829 - CD20 (L27) APC-Cy (TM) 7 641414 - CD20 (L27) APC-H7 345794 - CD20 (L27) PerCP 332781 - CD20 (L27) PerCP-Cy (TM) 5.5 345793 - CD20 (L27) PE 335828 - CD20 (L27) PE-Cy (TM) 7 655872 - CD20 (L27) V450
<p><b>We hereby declare that the above mentioned product(s) manufactured after 2017/10/01 complies with the above listed Directive(s) and its relevant transposition into national laws of the member states into which we place the devices.</b></p>	
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<b>Conformity assessment procedure:</b>	Annex III of the IVD Directive 98/79/EC.
<b>Product:</b>	337898 - CD22 (S-HCL-1) FITC 333145 - CD22 (S-HCL-1) APC 337899 - CD22 (S-HCL-1) PE
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<b>Conformity assessment procedure:</b>	Annex III of the IVD Directive 98/79/EC.
<b>Product:</b>	332782 - CD23 (EBVCS-5) PE 335036 - CD23 (EBVCS-5) APC
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<b>Conformity assessment procedure:</b>	Annex III of the IVD Directive 98/79/EC.
<b>Product:</b>	345796 - CD25 (2A3) FITC 340907 - CD25 (2A3) APC 341011 - CD25 (2A3) PE 335824 - CD25 (2A3) PE-Cy (TM) 7
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<b>Conformity assessment procedure:</b>	Annex III of the IVD Directive 98/79/EC.
<b>Product:</b>	345798 - CD33 (P67.6) FITC 345800 - CD33 (P67.6) APC 333146 - CD33 (P67.6) PerCP-Cy (TM) 5.5 345799 - CD33 (P67.6) PE 333952 - CD33 (P67.6) PE-Cy (TM) 7
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<b>Conformity assessment procedure:</b>	Annex III of the IVD Directive 98/79/EC.
<b>Product:</b>	345801 - CD34 FITC (8G12) 345804 - CD34 APC (8G12) 347222 - CD34 PerCP-Cy5.5 345803 - CD34 PerCP (8G12) 348811 - CD34 PE-Cy7 345802 - CD34 PE (8G12)
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<b>Conformity assessment procedure:</b>	Annex III of the IVD Directive 98/79/EC.
<b>Product:</b>	340909 - CD38 (HB-7) FITC 345807 - CD38 (HB-7) APC 345806 - CD38 (HB-7) PE 335825 - CD38 (HB-7) PE-Cy (TM) 7
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<b>Conformity assessment procedure:</b>	Annex III of the IVD Directive 98/79/EC.
<b>Product:</b>	345808 - CD45 (2D1) FITC 340910 - CD45 (2D1) APC 348815 - CD45 (2D1) APC-Cy7 641417 - CD45 (2D1) APC-H7 345809 - CD45 (2D1) PerCP 332784 - CD45 (2D1) PerCP-Cy (TM) 5.5 655873 - CD45 (2D1) V500-C
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<b>Conformity assessment procedure:</b>	Annex III of the IVD Directive 98/79/EC.
<b>Product:</b>	335039 - CD45RA (L48) FITC 337186 - CD45RA (L48) PE-Cy7
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<b>Conformity assessment procedure:</b>	Annex III of the IVD Directive 98/79/EC.
<b>Product:</b>	345810 - CD56 (MY31) PE -
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<b>Conformity assessment procedure:</b>	Annex III of the IVD Directive 98/79/EC.
<b>Product:</b>	345811 - CD56 (NCAM16.2) FITC 341027 - CD56 (NCAM16.2) APC 345812 - CD56 (NCAM16.2) PE 335826 - CD56 (NCAM16.2) PE-Cy (TM) 7
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<b>Conformity assessment procedure:</b>	Annex III of the IVD Directive 98/79/EC.
<b>Product:</b>	347407 - CD61 (RUU-PL 7F12) FITC 347408 - CD61 (RUU-PL 7F12) PerCP
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<b>Conformity assessment procedure:</b>	Annex III of the IVD Directive 98/79/EC.
<b>Product:</b>	333151 - CD71 (L01.1) FITC 337447 - CD71 (L01.1) APC
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