

**BD**

Declaration of Conformity

Manufacturer:	Becton, Dickinson and Company BD Biosciences 2350 Qume Drive San Jose, CA 95131 USA
Authorized Representative:	Benex Limited Pottery Road, Dun Laoghaire Co. Dublin, Ireland Tel:+353.1.202.5222/Fax: +353.1.202.5388
Conformity Assessment Procedure:	IVD Directive 98/79/EC, Annex III
Product(s) Conforming to IVD Directive:	347214 - CD138 FITC (MI15) 347215 - CD138 PE (MI15) 347216 - CD138 APC (MI15) 341107 - CD138 PerCP-Cy5.5 (MI15)

This Declaration of Conformity is issued under the sole responsibility of Becton, Dickinson and Company, BD Biosciences.

We hereby declare that the above mentioned product(s) complies with the above referenced Directive(s) and its relevant transposition into national laws of the member states into which we place the devices.

Name and Authority in San Jose:	<i>Shereen Dasler Dir Quality</i>
QA Authority Signature	Date
<i>[Signature]</i>	<i>01 aug 2019</i>



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Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	347400 - Anti-HLA-DR (L243) FITC 347403 - Anti-HLA-DR (L243) APC 335831 - Anti-HLA-DR (L243) APC-Cy (TM) 7 641411 - Anti-HLA-DR (L243) APC-H7 347402 - Anti-HLA-DR (L243) PerCP 339216 - Anti-HLA-DR (L243) PerCP-Cy (TM) 5.5 347401 - Anti-HLA-DR (L243) PE 335830 - Anti-HLA-DR (L243) PE-Cy (TM) 7 655874 - Anti-HLA-DR (L243) V450
<p>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.</p>	
Signed In San Jose:	2017/10/01
Name and Authority:	Paul Arrendell, WW VP Quality Management
Signature:	

Technical File Number:



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Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	333140 - Anti-TCR-a/b (WT31) FITC -
<p>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.</p>	
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Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	333141 - Anti-TCR- g/d (11F2) PE -
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Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	332789 - Anti-TdT (E17-1519) FITC 332791 - Anti-TdT (E17-1519) APC 332790 - Anti-TdT (E17-1519) PE
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Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	656046 - BD FACSDiva CS&T IVD Beads 656047 - BD FACSDiva CS&T IVD Beads
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Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	349202 - BD FACS (TM) Lysing Solution -
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Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	641778 - BD IntraSure Kit -
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Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	331356 - BD Oncomark (TM) Lambda/Kappa/CD20 -
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Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	349217 - BD Simultest IMK Plus -
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Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	333167 - CD1a (SK9) PE -
<p>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.</p>	
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Conformity Assessment Procedure:	IVD Directive 98/79/EC, Annex III
Product(s) Conforming to IVD Directive:	347404 - CD2 (S5.2) FITC 347405 - CD2 (S5.2) PE 341024 - CD2 (L303.1) APC 335821 - CD2 (L303.1) PE-Cy7
<p>This Declaration of Conformity is issued under the sole responsibility of Becton, Dickinson and Company, BD Biosciences.</p> <p>We hereby declare that the above mentioned product(s) complies with the above referenced Directive(s) and its relevant transposition into national laws of the member states into which we place the devices.</p>	
Name and Authority in San Jose:	Sherrie Daseler, WW Vice President, Quality Management
QA Authority Signature	Date
	25 Mar 2021

Document Number: 10000353627, Ver. B



Decl of Conf - CD2

NOTE: Print all pages prior to this page if providing it as a hard copy.

Version History		
Version	Description of Changes	Date of Completion
A	Initial release	01OCT2017
B	Updated to correct the clone for APC and PE-Cy7 from S5.2 to L303.1. This change is supported by a memo (10000524574, Ver. B) for correction of the clone.	See watermark



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Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	345763 - CD3 (SK7) FITC 345767 - CD3 (SK7) APC 341110 - CD3 (SK7) APC-Cy7 641415 - CD3 (SK7) APC-H7 345764 - CD3 (SK7) FITC 345766 - CD3 (SK7) PerCP 332771 - CD3 (SK7) PerCP-Cy5.5 345765 - CD3 (SK7) PE 341111 - CD3 (SK7) PE-Cy7 652896 - CD3 (SK7) V500-C
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Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	345768 - CD4 (SK3) FITC 345771 - CD4 (SK3) APC 341115 - CD4 (SK3) APC-Cy (TM) 7 345770 - CD4 (SK3) PerCP 332772 - CD4 (SK3) PerCP-Cy (TM) 5.5 345769 - CD4 (SK3) PE 348809 - CD4 (SK3) PE-Cy (TM) 7
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Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	345781 - CD5 (L17F12) FITC 345783 - CD5 (L17F12) APC 341109 - CD5 (L17F12) PerCP-Cy (TM) 5.5 345782 - CD5 (L17F12) PE 348810 - CD5 (L17F12) PE-Cy (TM) 7
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Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	345772 - CD8 (SK1) FITC 345775 - CD8 (SK1) APC 348813 - CD8 (SK1) APC-Cy (TM) 7 345774 - CD8 (SK1) PerCP 341050 - CD8 (SK1) PerCP-Cy (TM) 5.5 345773 - CD8 (SK1) PE 335822 - CD8 (SK1) PE-Cy (TM) 7
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Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	332775 - CD10 FITC (HI10a) 332777 - CD10 APC (HI10a) 341112 - CD10 PE-Cy7 (HI10a) 332776 - CD10 PE (HI10a)
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Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	333142 - CD11b (D12) PE 333143 - CD11b (D12) APC
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Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	333149 - CD11c (S-HCL-3) PE 333144 - CD11c (S-HCL-3) APC
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Conformity assessment procedure:	Annex III of the IVD Directive 98/79/EC.
Product:	347406 - CD13 (L138) PE 338439 - CD13 (L138) PE-Cy7
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