

Manufacturer: Becton, Dickinson and Company

BD Biosciences 2350 Qume Drive

San Jose, CA 95131, USA

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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

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.

Signed In San Jose: 2017/10/01

Name and Authority: Paul Arrendell, WW VP Quality Management

Signature: Paul Arrendell

Technical File Number: