



Document:
Declaration of Conformity

Document #: Revision 4.0
GLB-QS-TMP-0029

Declaration of Conformity

Beckman Coulter, Inc. hereby ensures and declares that the product(s) listed below comply with the requirement of the European Union In-vitro Diagnostics Medical Device Directive 98/79/EC.

Beckman Coulter, Inc. assure et déclare par la présente que le(s) produit(s) listé(s) ci-dessous sont conformes aux exigences de la directive européenne 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro.

Beckman Coulter, Inc. dichiara ed assicura che i prodotti qui elencati sono conformi ai requisiti della direttiva comunitaria 98/79/CE relative ai dispositivi medico-diagnostici in vitro.

Beckman Coulter, Inc. versichert und erklärt hiermit, daß die im Folgenden aufgeführten Producte den Auflagen der IVD-Richtlinie für In-vitro-Diagnostika der Europäischen Union (98/79/EC) entsprechen.

Beckman Coulter, Inc. asegura y declara que los productos listados a continuación cumplen con los requisitos establecidos en la directiva 98/79/EC de la Comunidad Europea para dispositivos médicos de diagnóstico in vitro.

Product(s) /Produkt(e) /Prodotto(i) / Produit(s) / Producto(s):

Product Name	Part Number
COULTER 6C Cell Control	A59925

Authorized Representative (AR)
Beckman Coulter Eurocenter S.A.
22, rue Juste-Olivier
Case Postale 1044
CH- 1260 Nyon 1, Switzerland

Conformity Assessment Procedure
Annex III - Self-Declared

Classification:
General

GMDN Code(s): 55866


Nery Ortiz
Sr. Manager Regulatory Affairs

17 Jan 2022
Date



Beckman Coulter Inc.
250 S. Kraemer Blvd.
Brea, CA 92821

Document Control
Issue Date: December 5, 2008
Revision Level: 4.0
Revision Date: January 17, 2022
Starting Lot #: 4812240K
Filename: A59925DEC