



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**

COULTER 6C Cell Control

**Part Number**

A59925

**Authorized Representative (AR)**

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**Conformity Assessment Procedure**

Annex III - Self-Declared

**Classification:**

General

**GMDN Code(s):** 55866

Nery Ortiz  
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17 Jan 2022  
Date



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**Document Control**

Issue Date: December 5, 2008

Revision Level: 4.0

Revision Date: January 17, 2022

Starting Lot #: 4812240K

Filename: A59925DEC