



Document:

Declaration of Conformity

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**Declaration of Conformity**  
**BCCP0038**

## 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 relativa ai dispositivi medico-diagnostici in vitro.

*Beckman Coulter Inc.* versichert und erklärt hiermit, daß die im Folgenden aufgeführten Produkte 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):**

COULTER Latron CP-X Control  
Part Number 628024

GMDN Code  
55864

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**Conformity Assessment Procedure**  
Annex III - Self-Declared

**Classification:**  
General

  
Radha Goolabsingh, RA Senior Manager

03/16/18  
Date



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