



Document:

**Declaration of Conformity**

Document #:

Revision 4.0

**GLB-QS-TMP-0029**

# Declaration of Conformity

**Beckman Coulter Ireland, 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 Ireland, 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 Ireland, 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 Ireland, 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 Ireland, 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 DxH  
Diff Pack

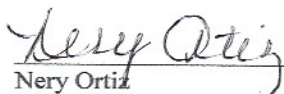
**Part Number**  
628020

**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):** 55855

  
Nery Ortiz

Sr. Manager Regulatory Affairs

01 Nov 2021  
Date



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

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