



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 DxH Cell Lyse, Part Number 628018

Authorized Representative (AR)

Beckman Coulter Eurocenter S.A.
22, rue Juste-Olivier
Case Postale 1044
CH – 1260 Nyon 1, Switzerland
Tel: +41 (0) 22 3645 36 11

Conformity Assessment Procedure

Annex III - Self-Declared

Classification:

General

Radha Goolabsingh, RA Senior Manager

Date



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

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