

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 relativa ai dispositivi medico-diagnostici in vitro.

Beckman Coulter Ireland 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 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):

Part Number	Description	GMDN
C49513	DxU 850m Iris	35918
C76947	DxU 840m Iris	35918

EU Directive (s) /EU-Richtlinien /Direttiva(e) Europea / Directive(s) Europennes/ / Directiva(s) Europeas:

In Vitro Diagnostic Directive 98/79/EC

Low voltage (2014/35/EU)

Electromagnetic compatibility (2014/30/EU)

Machinery Directive (2006/42/EC)

RoHS Directive (2011/65/EU)

Standard(s) /Norm(en) /Norma(e) / Norme(s) / Norma(s):

EMC: EN 61326-1:2013
EN 61326-2-6:2013
Product Safety: EN 61010-1:2010
EN 61010-2-101:2018
EN 61010-2-081:2015
RoHS: EN 63000-2018

Conformity Assessment Procedure

Annex III –Self-declared;

CE Mark Affixed

Classification: General IVD

Notified Body: N/A

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Samy Puccio,
Senior Manager, Regulatory Affairs

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Date



Beckman Coulter Ireland, Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare – Ireland
www.beckmancoulter.com