

	Document:	Document #:	Revision
	Declaration of Conformity	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 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):

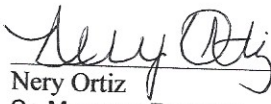
Product Name	Part Number (PN)
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iQ Calibrator (Pack)	800-3103
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Conformity Assessment Procedure
Annex III –Self-declared

Classification:
General IVD (non Annex II, non self test)

GMDN Code(s):
42064


Nery Ortiz
Sr. Manager Regulatory Affairs

09 Jun 2021
Date



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