

	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 relativa 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 Part Number (PN)

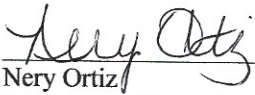
iQ Precision Kit 800-3014

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



Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare, Ireland

Document Control
Issue Date: 12/14/2018
Revision Level:2.0
Revision Date: 06/08/2021
Starting Lot #: N/A
Filename: 8003014DEC