# 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 Produckte 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 listadoes 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

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