Tiêu chuẩn chủ sở hữu TTBYT công bố áp dụng

Tài liệu được xác nhận bằng chữ ký số và có hiệu lực kể từ ngày ký.

Hà Nội, ngày 08 tháng 10 năm 2019

Người đại diện hợp pháp của cơ sở

Digitally signed by CÔNG TY TNHH KỸ THUẬT NAM PHƯƠNG
Date: 2019.10.08 16:02:35 +07'00'

Giám đốc

Trịnh Diệu Hương

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 Produckte 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 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):

IsoFlow Sheath Fluid, Part Number 8546859

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, Date 08/02/18
Director of Regulatory Affairs

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

Document Control
Issue Date: November 12, 2003
Revision Level: 8.0
Revision Date: August 2, 2018
Manufactured in Florence, Kentucky
Starting Lot #: 50193F
Manufactured in Krefeld, Germany
Starting Lot#: 007512K
Filename: 8546859DEC

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 Diagnostic 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.

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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):

Iso-Flow™ Sheath Fluid, Part Number 8547008

[AR] Authorized Representative

Beckman Coulter Ireland Inc.
Mervue Business Park
Mervue Galway, Ireland
Tel: +353 91 7740 68 Fax: + 353 91 751404

Conformity Assessment Procedure
Annex III, Self-Declared

Staff Regulatory Affairs Specialist

11/23/10
Date

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