



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 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):

MicroScan Neg Urine Combo 81, B1016-191

Authorized Representative (AR)

Beckman Coulter Eurocenter S.A.
22, rue Juste-Olivier
Case Postale 1044
CH- 1260 Nyon 1, Switzerland

Conformity Assessment Procedure
Annex III –Self-Declared

Classification:
General

GMDN Code(s):
58605

Jose Untalan
Director Quality & Regulatory Affairs

21 NOV 2018
Date



Beckman Coulter, Inc.
250 S. Kraemer Blvd. E1.SE.01
Brea, CA 92821, USA

Document Control

Issue Date: November 21, 2018
Revision Level: 1.0
Revision Date: Initial Release
Starting Lot #: N/A
Filename: DoC B1016-191 NUC81