



Certificate of Analysis

LEGAL ADDRESS:

Beckman Coulter, Inc.
250 S. Kraemer Boulevard
Brea, CA 92821

MANUFACTURER ADDRESS:

Beckman Coulter, Inc.
2040 Enterprise Boulevard
West Sacramento, CA 95691
Tel: 1-800-677-7226

PRODUCT DESCRIPTION:	PBC29
MATERIAL/CATALOG NO.	B1016-145
LOT No. / SERIAL NUMBER:	2020-09-12
EXPIRATION DATE: (YYYY-MM-DD)	2020-09-12
MANUFACTURED DATE: (YYYY-MM-DD)	2019-09-12
RELEASE DATE: (YYYY-MM-DD)	2019-09-16

This product was certified by the responsible Quality organization to conform to the performance and Quality System requirements of Beckman Coulter.



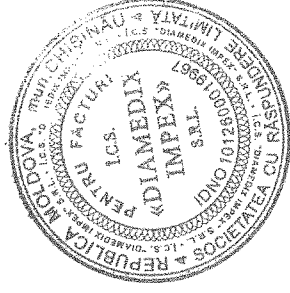
Performance: The panel lot has been tested and passed Quality Control specifications. Testing was completed utilizing QC organisms with known reactions and MIC ranges as applicable. All MIC endpoints and/or biochemical reactions were within specifications (see current package insert.)

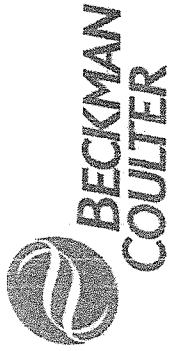
Handwritten signature

Quality Assurance Representative

2019-09-16

Date (yyyy-mm-dd)





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 relative 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 MicroSTREP plus Panel Type 1, B1027-201

Authorized Representative (AR)
Beckman Coulter Eurocenter S.A.
22, rue Juste-Olivier
Case Postale 1044
CH - 1260 Nyon 1, Switzerland
Tel: +41 (0) 22 365 6 11

Conformity Assessment Procedure
Annex III, Self-Declared

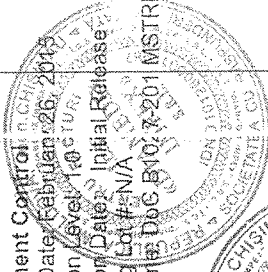

Date

Robert Eusebio
Director Regulatory Affairs



Beckman Coulter, Inc.
230 S. Kraemer Blvd, ELSE.01
Brea, CA 92821, USA

Document Control
Issue Date: February 26, 2015
Revision Level: 1.06 IUR
Revision Date: Initial Release
Starting Lot #: N/A
Filename: Doc B107-201 MSTRP+1





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 conforme(s) 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 relative ai dispositivi medico-diagnostici in vitro.

Beckman Coulter Inc. versichert und erklärt hiermit, daß die im Folgenden aufgeführten Produkte den Anforderungen 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 Inoculum Water, 3 ml (60 pack) B1015-2

Authorized Representative (AR)
Beckman Coulter Eurocenter S.A.
22, rue Juste-Olivier
Case Postale 1044
CH - 1260 Nyon 1, Switzerland
Tel: +41 (0) 22 365 31 11

Conformity Assessment Procedure
Annex III, Self-Declared

Classification
General

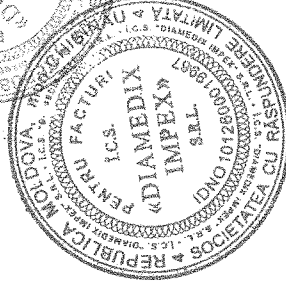
Robert Eusebio
Director Regulatory Affairs

Robert Eusebio
Date 2015-03-06

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



Document Control
Issue Date: February 17, 2015
Revision Level: 1.0
Revision Date: Initial Release
Starting Lot #: N/A
Filename: Doc B1015-2 Inoculum Water,
3 ml 60 pk



SIEMENS



Declaration of Conformity

We hereby declare that the in vitro diagnostic devices and / or accessories described below conform to the Annex I Essential Requirements of Directive 98/79/EC.

Note: Product labeling may show Siemens Healthcare Diagnostics Inc. or Dade Behring Inc. during the labeling transition period.

Product:

MicroScan[®] Inoculum Water with PLURONIC[®]

Cat. No. (REF)

B1015-7

**Manufacturer:
Address:**

Siemens Healthcare Diagnostics Inc.
2040 Enterprise Blvd.
West Sacramento, CA 95691 USA

**EU Authorized
Representative:**

Siemens Healthcare Diagnostics Ltd.
Sir William Siemens Sq.
Frimley, Camberley, UK GU16 8QD

Date:

2008-07-01

Authorization:

Signature *Robert Eusebio*

Print: Robert Eusebio

Senior Quality Management Representative

