



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 hiernit, 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.

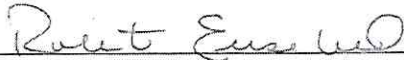
Product(s) /Produkt(e) /Prodotto(i) / Produit(s) / Producto(s):

MicroScan 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 36 11

Conformity Assessment Procedure
Annex III, Self-Declared

Classification
General



2015-03-06
Date

Robert Eusebio
Director Regulatory Affairs



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



DECLARATION OF CONFORMITY

Beckman Coulter Inc. hereby ensures and declares that the product(s) listed below comply with the requirement of the *In-Vitro* Diagnostic Medical Devices Regulation 2017/746.

This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.

EU Directive(s)

In-Vitro Diagnostic Medical Devices Regulation (2017/746/EU)

ROHS Directive (2015/863/EU)

Product(s):

MicroScan RENOK Rehydrating / Inoculating System B1018-14
MicroScan RENOK Disposable-D-Inoculator Sets B1013-4
MicroScan RENOK Disposable-D-Inoculator Sets B1013-5
MicroScan RENOK Disposable-R-Inoculator Sets B1013-6

Device Group:

W020301

BUDI-DI:

15099501MCRENOKP6

Risk Class:

Class A, Rule 5(b)

Intended Purpose:

Intended Use: The RENOK Rehydrating / Inoculating System is a manual pipettor that simultaneously rehydrates and inoculates MicroScan panels (conventional dried panels or designated rapid panels) used in conjunction with disposable MicroScan inoculator sets that consist of a transfer lid (to hold and dispense the inoculum) and a seed trough (to contain the inoculum).

MicroScan RENOK Disposable D-Inoculator Sets is for use with MicroScan RENOK.

MicroScan RENOK Disposable R-Inoculator Sets is for use with MicroScan RENOK.

Intended User: This product is intended for laboratory professional use.

Clinical Relevance: Not applicable, product is an IVD accessory.

Common Specification(s):

None

Authorized Representative (AR)

Beckman Coulter Ireland, Inc.
Lismeehan, O'Callaghan's Mills
Co. Clare Ireland
+(353) (0) 65 683 1100

AR SRN: IE-AR-000000886

Conformity Assessment Procedure:

Conformity Assessment based on a Quality Management System and on Technical Documentation in accordance with Annex II and III, and declaration of conformity in accordance with Article 17 and Annex IV.

Signed for and on behalf of Beckman Coulter, Inc. the Legal Manufacturer.

Name: David Weissman 2022-08-12
Title: Senior Manager, Regulatory Affairs, PRRC
Place of Issue: Beckman Coulter, Inc., West Sacramento, CA, USA



Beckman Coulter, Inc.
250 South Kraemer Blvd. Brea, California 92821, USA
+(1) 800-854-3633
Manufacturer SRN: US-MF-000010288
IVDR Certificate Number: N/A

Document Control

Issue Date:	2022-03-08
Revision Level:	1.4
Starting Lot :	B1018-14 SN: 402190 B1013-4 & B1013-5 DOM 2022-05-16, B1013-6 DOM 2022-04-17 & 2022-07-25
Starting RoHS #:	2021-PEC-089
DoC Filename:	BRE-0148



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 Neg Combo Panel Type 58, B1016-158

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 36 11

Conformity Assessment Procedure
Annex III, Self-Declared

Classification
General



2015-03-06
Date

Robert Eusebio
Director Regulatory Affairs



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

Document Control
Issue Date: February 26, 2015
Revision Level: 1.0
Revision Date: Initial Release
Starting Lot #: N/A
Filename: DoC B1016-158 NC58



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 hiernit, 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):

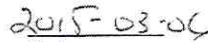
MicroScan Reagent, HNID Indole 30 ml, B1015-15

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 36 11

Conformity Assessment Procedure
Annex III, Self-Declared

Classification
General




Date

Robert Eusebio
Director Regulatory Affairs



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

Document Control
Issue Date: February 26, 2015
Revision Level: 1.0
Revision Date: Initial Release
Starting Lot #: N/A
Filename: DoC B1015-15 HNID Indole
30ml



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 Reagent, Suflanic Acid 0.8%, 30 ml B1010-44A

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 36 11

Conformity Assessment Procedure
Annex III, Self-Declared

Classification
General



2015-03-06
Date

Robert Eusebio
Director Regulatory Affairs



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

Document Control
Issue Date: February 26, 2015
Revision Level: 1.0
Revision Date: Initial Release
Starting Lot #: N/A
Filename: DoC B1010-44A Suflanic Acid 0.8%, 30 ml



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 Reagent, Dimethylalphanaphthylamine .5%NN 30 ml
B1010-45A*

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 36 11

Conformity Assessment Procedure
Annex III, Self-Declared



2015-03-06
Date

*Robert Eusebio
Director Regulatory Affairs*



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

Document Control
Issue Date: February 26, 2015
Revision Level: 1.0
Revision Date: Initial Release
Starting Lot #: N/A
Filename: DoC B1010-45A
Dimethylalphanaphthylamine .5%NN
30 ml



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 hiemit, 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 Reagent, Rapid Indole-F, 30 ml B1015-17

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 36 11

Conformity Assessment Procedure
Annex III, Self-Declared

Classification
General



2015-03-06
Date

Robert Eusebio
Director Regulatory Affairs



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

Document Control
Issue Date: February 18, 2015
Revision Level: 1.0
Revision Date: Initial Release
Starting Lot #: N/A
Filename: DoC B1015-17 Reagent,
Rapid Indole-F, 30ml



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 Producte 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 Reagent, Ferric Chloride 10%, 30 ml B1010-48A

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 36 11

Conformity Assessment Procedure
Annex III, Self-Declared

Classification
General



2015-03-06
Date

Robert Eusebio
Director Regulatory Affairs



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

Document Control
Issue Date: February 26, 2015
Revision Level: 1.0
Revision Date: Initial Release
Starting Lot #: N/A
Filename: DoC B1010-48A Ferric
Chloride 10% 30ml



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 Reagent Kovac's 30ml, B1010-41A

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 36 11

Conformity Assessment Procedure
Annex III, Self-Declared

Classification
General



2015-03-06
Date

Robert Eusebio
Director Regulatory Affairs



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

Document Control
Issue Date: February 26, 2015
Revision Level: 1.0
Revision Date: Initial Release
Starting Lot #: N/A
Filename: DoC B1010-41A Kovacs 30ml



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 Reagent Alpha Naphthol 1.5 gm, B1010-42A

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 36 11

Conformity Assessment Procedure
Annex III, Self-Declared

Classification
General



2015-03-06
Date

Robert Eusebio
Director Regulatory Affairs



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

Document Control
Issue Date: February 26, 2015
Revision Level: 1.0
Revision Date: Initial Release
Starting Lot #: N/A
Filename: DoC B1010-42A Alpha
Naphthol 1.5gm



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 MHB/LHB (3%) Broth, 25 ml (10 pk) B1015-25

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 36 11

Conformity Assessment Procedure
Annex III, Self-Declared

Classification
General

Robert Eusebio

2015-03-06
Date

Robert Eusebio
Director Regulatory Affairs



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

Document Control
Issue Date: February 18, 2015
Revision Level: 1.0
Revision Date: Initial Release
Starting Lot #: N/A
Filename: DoC B1015-25 LHB Broth,
25ml



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 Producte 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 Pos Breakpoint Combo Panel Type 29, B1016-145

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 36 11

Conformity Assessment Procedure
Annex III, Self-Declared

Classification
General



2015-03-06
Date

Robert Eusebio
Director Regulatory Affairs



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

Document Control
Issue Date: February 20, 2015
Revision Level: 1.0
Revision Date: Initial Release
Starting Lot #: N/A
Filename: DoC B1016-145 PBC29



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 Peptidase Reagent, 30 ml, B1012-30B

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 36 11

Conformity Assessment Procedure
Annex III, Self-Declared

Classification
General



2015-03-06
Date

Robert Eusebio
Director Regulatory Affairs



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 B1012-30B Peptidase
30ml



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 Producte 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 Reagent, Potassium Hydroxide 40%, 30 ml B1010-43A

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 36 11

Conformity Assessment Procedure
Annex III, Self-Declared

Classification
General



2015-03-06
Date

Robert Eusebio
Director Regulatory Affairs



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

Document Control
Issue Date: February 26, 2015
Revision Level: 1.0
Revision Date: Initial Release
Starting Lot #: N/A
Filename: DoC B1010-43A Potassium Hydroxide 40% 30ml

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: Siemens Healthcare Diagnostics Inc.
Address: 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

