



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 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 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



2015-03-01
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 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



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 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, Sulfanilic 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 Sulfanilic
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.

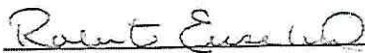
Beckman Coulter Inc. asegura y declara que los productos listados a continuación cumplen con los requisitos establecidos en la directiva 98/79/EC de la Comunidad Europea para dispositivos médicos de diagnóstico in vitro.

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. EI.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. vorsichert 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

Robert Eusebio

2015-03-05
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 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, 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 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 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

