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Date: 2021.02.11 09:18:58 EET
Reason: MoldSign Signature
Location: Moldova

BECKMAN COULTER

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:	NC58
MATERIAL/CATALOG NO.	B1016-158
LOT NO. / SERIAL NUMBER:	2020-08-29
EXPIRATION DATE: (YYYY-MM-DD)	2020-08-29
MANUFACTURED DATE: (YYYY-MM-DD)	2019-08-29
RELEASE DATE: (YYYY-MM-DD)	2019-09-03

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.)

Quality Assurance Representative

2019-09-03
Date (yyyy-mm-dd)

REPUBLICA MOLDOVA, mun. CHISINAU
PENTRU FACTURI
I.C.S. «DIAMEDIX IMPEX» S.R.L.
IDNO 1012600019967
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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.)

Quality Assurance Representative — Date (yyyy-mm-dd): 2019-09-16

REPUBLICA MOLDOVA, I.C.S. «DIAMEDIX IMPEX» S.R.L. PENTRU FACTURI, IDNO 1012600018967, SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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 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 requis tos 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 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 26, 2015
Revision Level: 1.0
Revision Date: Initial Release
Starting Lot #: N/A
Filename: DoC B1027-201 MSTRP+1

REPUBLICA MOLDOVA, mun. CHISINAU, I.C.S. PENTRU FACTURI I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019867 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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 Produckte den Auf agen 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):

MicroScan Inoculum Water, 3 ml (60 pack) B1015-2

Authorized Represe ntative (AR)
Beckman Coulter Eur ocenter 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 17, 2015
Revision Level: 1.0
Revision Date: Initia Release
Starting Lot #: N/A
Filename: DoC B1015-2 Inoculum Water, 3 ml 60 pk

REPUBLICA MOLDOVA, MUNICIPIUL CHIŞINĂU, I.C.S. "DIAMEDIX IMPEX" S.R.L., PENTRU FACTURI, I.C.S. «DIAMEDIX IMPEX» S.R.L., IDNO 1012600019067, SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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

REPUBLICA MOLDOVA MUN. CHIŞINĂU PENTRU FACTURI I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019967 SOCIETATEA CU RĂSPUNDERE LIMITATĂ