

SIEMENS

EC Declaration of Conformity



We hereby declare that the product described below conforms to all applicable requirements of Council Directive 98/79/EC for in vitro diagnostic medical devices.

Legal Manufacturer: Siemens Healthcare Diagnostics Inc.
500 GBC Drive, Mailstop 514, P.O. Box 6101
Newark, DE, 19714, USA

Place of Manufacture: Siemens Healthcare Diagnostics Inc.
500 GBC Drive, Mailstop 514, P.O. Box 6101
Newark, DE, 19714, USA

EC Authorized Representative: Siemens Healthcare Diagnostics Ltd.
Sir William Siemens Square
Frimley, Camberley, GU16 8QD, UK

Product Name: Dimension® Triglycerides Flex® reagent cartridge

Catalogue Number (REF): DF69A

Siemens Material Number (SMN): 10444906

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Control Number: DoC_DM_TGL_DF69A

Version: 2.0

*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Inc.
This declaration supersedes any declaration issued previously for the same product.*

Signature:

Rebecca S. Ayash
Sr. Director Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
Newark, DE 19714

2015/10/27

Date
[YYYY-MM-DD]



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Newark, DE, 19714, USA

EC Authorized Representative: Siemens Healthcare Diagnostics Ltd.
Sir William Siemens Square
Frimley, Camberley, GU16 8QD, UK

Product Name: Dimension® Alanine Aminotransferase Flex® reagent cartridge

Catalogue Number (REF): DF143

Siemens Material Number (SMN): 10475530

Classification: General IVD

Conformity Assessment Route: ANNEX III

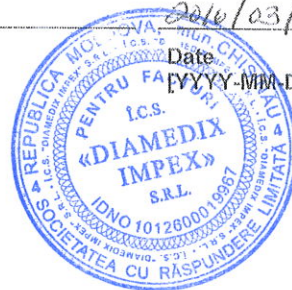
Document Control Number: DoC_DM_ALTI_DF143

Version: 2.0

*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Inc.
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Signature:

Rebecca S. Ayash
Sr. Director Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
Newark, DE 19714



Date
[YYYY-MM-DD]

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Newark, DE, 19714, USA

EC Authorized Representative: Siemens Healthcare Diagnostics Ltd.
Sir William Siemens Square
Frimley, Camberley, GU16 8QD, UK

Product Name: Dimension® Aspartate Aminotransferase Flex® reagent cartridge

Catalogue Number (REF): DF41A

Siemens Material Number (SMN): 10444959

Classification: General IVD

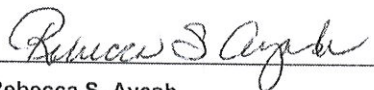
Conformity Assessment Route: ANNEX III

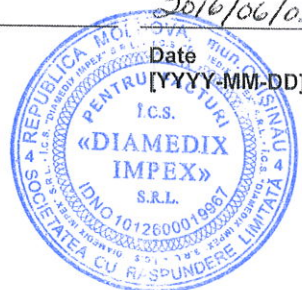
Document Control Number: DoC_DM_AST (GOT)_DF41A

Version: 2.0

*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Inc.
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Signature:


Rebecca S. Ayash
Sr. Director Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
Newark, DE 19714



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500 GBC Drive, Mailstop 514, P.O. Box 6101
Newark, DE, 19714, USA

EC Authorized Representative: Siemens Healthcare Diagnostics Ltd.
Sir William Siemens Square
Frimley, Camberley, GU16 8QD, UK

Product Name: Dimension® Total Bilirubin Flex® reagent cartridge

Catalogue Number (REF): DF167

Siemens Material Number (SMN): 10444957

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Control Number: DoC_ DM_TBI_DF167

Version: 2.0

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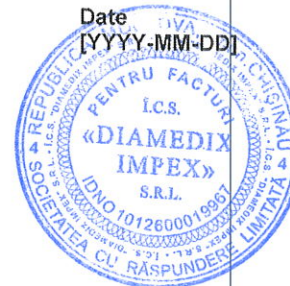
Signature:

Rebecca S. Ayash
Sr Director Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
Newark, DE 19714

Date

[YYYY-MM-DD]

2016/10/27



EC DECLARATION OF CONFORMITY

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Newark, DE, 19714, USA

EC Authorized Representative: Siemens Healthcare Diagnostics Ltd.
Sir William Siemens Square
Frimley, Camberley, GU16 8QD, UK

Product Name: Dimension® Cuvette Cartridge

Catalogue Number (REF): D828

Siemens Material Number (SMN): 10445042

Classification: General IVD

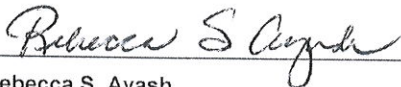
Conformity Assessment Route: ANNEX III

Document Control Number: DoC_DM_Cuvette Cartridge_D828

Version: 3.0

*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Inc.
This declaration supersedes any declaration issued previously for the same product.*

Signature:


Rebecca S. Ayash
Sr. Director Regulatory Affairs
Siemens Healthcare Diagnostics, Inc.
Newark, DE 19714

Date
[YYYY-MM-DD]

2016/08/05



EC DECLARATION OF CONFORMITY

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Newark, DE, 19714, USA

Place of Manufacture: Siemens Healthcare Diagnostics Inc.
500 GBC Drive, Mailstop 514, P.O. Box 6101
Newark, DE, 19714, USA

EC Authorized Representative: Siemens Healthcare Diagnostics Ltd.
Sir William Siemens Square
Frimley, Camberley, GU16 8QD, UK

Product Name: Dimension® Direct Bilirubin Flex® reagent cartridge

Catalogue Number (REF): DF125

Siemens Material Number (SMN): 10444956

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Control Number: DoC_DM_DBI_DF125

Version: 2.0

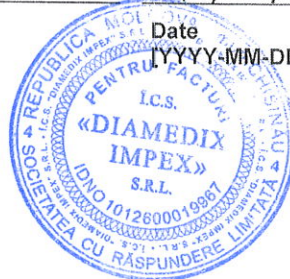
*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Inc.
This declaration supersedes any declaration issued previously for the same product.*

Signature:

Rebecca S. Ayash
Sr. Director Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
Newark, DE 19714

2016/06/22

Date
[YYYY-MM-DD]



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Place of Manufacture: Siemens Healthcare Diagnostics Inc.
500 GBC Drive, Mailstop 514, P.O. Box 6101
Newark, DE, 19714, USA

EC Authorized Representative: Siemens Healthcare Diagnostics Ltd.
Sir William Siemens Square
Frimley, Camberley, GU16 8QD, UK

Product Name: Dimension® Creatinine Flex® reagent cartridge

Catalogue Number (REF): DF33B

Siemens Material Number (SMN): 10872079

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Control Number: DoC_DM_CRE2_DF33B

Version: 2.0

*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Inc.
This declaration supersedes any declaration issued previously for the same product.*

Signature:

Rebecca S. Ayash
Sr. Director Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
Newark, DE 19714

2016/08/12

Date
[YYYY-MM-DD]



EC DECLARATION OF CONFORMITY

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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: Dimension® Uric Acid Flex® reagent cartridge (URCA)

Cat. No. (REF) DF77

Manufacturer Address: Siemens Healthcare Diagnostics Inc.
500 GBC Drive
P.O. Box 6101
Newark, Delaware 19714-6101

EU Authorized Representative: Siemens Healthcare Diagnostics Ltd.
Sir William Siemens Sq.
Frimley, Camberley, UK GU16 8QD

Date: 2008-07-01

Authorization:

Signature Julie L. Feaster

Print Julie L. Feaster
Regulatory Affairs & Quality Systems
Representative

Siemens Healthcare Diagnostics Inc.

P.O. Box 6101
Newark, DE 19714-6101



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: Dimension® Urea Nitrogen Flex® reagent cartridge (BUN)

Cat. No. (REF) DF21

Manufacturer Address: Siemens Healthcare Diagnostics Inc.
500 GBC Drive
P.O. Box 6101
Newark, Delaware 19714-6101

EU Authorized Representative: Siemens Healthcare Diagnostics Ltd.
Sir William Siemens Sq.
Frimley, Camberley, UK GU16 8QD

Date: 2008-07-01

Authorization:

Signature Julie L. Feaster

Print Julie L. Feaster
Regulatory Affairs & Quality Systems
Representative

Siemens Healthcare Diagnostics Inc.

P.O. Box 6101
Newark, DE 19714-6101



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Place of Manufacture: Siemens Healthcare Diagnostics Inc.
500 GBC Drive, Mailstop 514, P.O. Box 6101
Newark, DE, 19714, USA

EC Authorized Representative: Siemens Healthcare Diagnostics Ltd.
Sir William Siemens Square
Frimley, Camberley, GU16 8QD, UK

Product Name: Dimension® Iron Flex® reagent cartridge

Catalogue Number (REF): DF85

Siemens Material Number (SMN): 10444945

Classification: General IVD

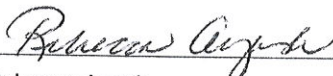
Conformity Assessment Route: ANNEX III

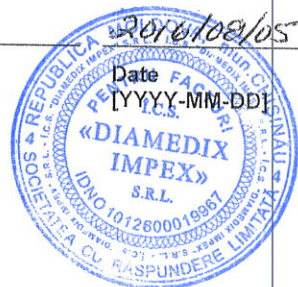
Document Control Number: DoC_DM_IRON_DF85

Version: 2.0

*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Inc.
This declaration supersedes any declaration issued previously for the same product.*

Signature:


Rebecca Ayash
Senior Director Regulatory Affairs
Siemens Healthcare Diagnostics
Newark, DE 19714



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Newark, DE, 19714, USA

EC Authorized Representative: Siemens Healthcare Diagnostics Ltd.
Sir William Siemens Square
Frimley, Camberley, GU16 8QD, UK

Product Name: Dimension® Albumin Flex® reagent cartridge

Catalogue Number (REF): DF13

Siemens Material Number (SMN): 10444975

Classification: General IVD

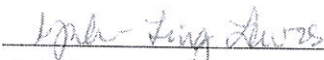
Conformity Assessment Route: ANNEX III

Document Control Number: DoC_DM_ALB_DF13

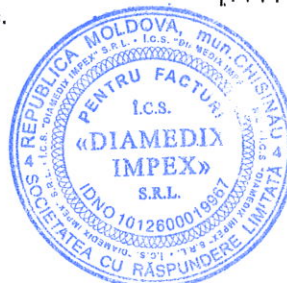
Version: 2.0

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Signature:


Yuk-Ting Lewis
Director Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
Newark, DE 19714

2017-09-11
Date
[YYYY-MM-DD]



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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: Dimension® Total Protein Flex® reagent cartridge (TP)

Cat. No. (REF) DF73

Manufacturer Address: Siemens Healthcare Diagnostics Inc.
500 GBC Drive
P.O. Box 6101
Newark, Delaware 19714-6101

EU Authorized Representative: Siemens Healthcare Diagnostics Ltd.
Sir William Siemens Sq.
Frimley, Camberley, UK GU16 8QD

Date: 2008-07-01

Authorization:

Signature Julie L. Feaster

Print Julie L. Feaster
Regulatory Affairs & Quality Systems
Representative

Siemens Healthcare Diagnostics Inc.

P.O. Box 6101
Newark, DE 19714-6101



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Place of Manufacture: Siemens Healthcare Diagnostics Inc.
500 GBC Drive, Mailstop 514, P.O. Box 6101
Newark, DE, 19714, USA

EC Authorized Representative: Siemens Healthcare Diagnostics Ltd.
Sir William Siemens Square
Frimley, Camberley, GU16 8QD, UK

Product Name: Dimension® Glucose Flex® reagent cartridge

Catalogue Number (REF): DF40

Siemens Material Number (SMN): 10444971

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Control Number: DoC_DM_GLUC_DF40

Version: 2.0

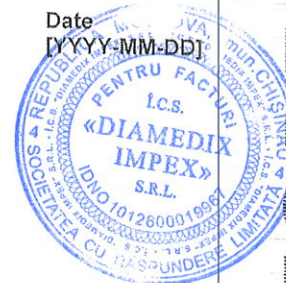
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Signature:

Rebecca S. Ayash
Sr. Director Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
Newark, DE 19714

2016/09/11

Date
[YYYY-MM-DD]



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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: Dimension® Cholesterol Flex® reagent cartridge (CHOL)

Cat. No. (REF) DF27

Manufacturer Address: Siemens Healthcare Diagnostics Inc.
500 GBC Drive
P.O. Box 6101
Newark, Delaware 19714-6101

EU Authorized Representative: Siemens Healthcare Diagnostics Ltd.
Sir William Siemens Sq.
Frimley, Camberley, UK GU16 8QD

Date: 2008-07-01

Authorization:

Signature

Print Julie L. Feaster
Regulatory Affairs & Quality Systems
Representative

Siemens Healthcare Diagnostics Inc.

P.O. Box 6101
Newark, DE 19714-6101

