

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

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:

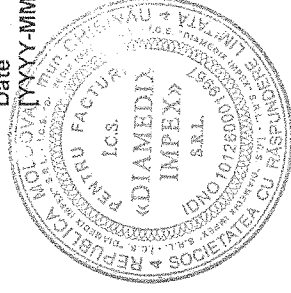
Rebecca S Ayash

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

2016/08/05

Date

YYYY-MM-DD



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® Cholesterol Flex® reagent cartridge (CHOL)

Cat. No. (REF) DF27

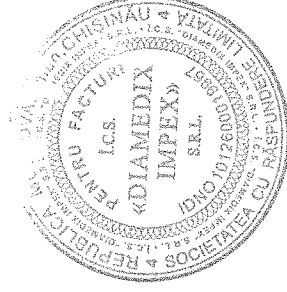
Manufacturer Address: Siemens Healthcare Diagnostics Inc.
500 GBC Drive
P.O. Box 6101
Newark, Delaware 19714-6101

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

Date: 2008-07-01

Authorization: Signature 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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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

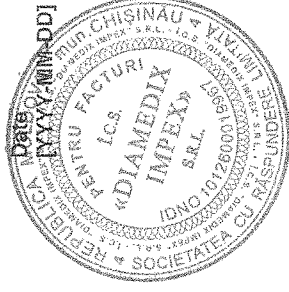
Document Control Number: DoC_DM_TGL_DF69A

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:  _____ *2015/10/27*

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



EC DECLARATION OF CONFORMITY

SIEMENS

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® 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

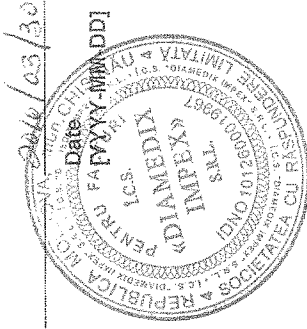
Version:

2.0

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Signature:

Rebecca S. Ayash
Sr. Director Regulatory Affairs
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Newark, DE 19714



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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® 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 **Date** 2016/10/27

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

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.
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Signature:

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

Date: 2016/06/22



EC DECLARATION OF CONFORMITY

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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® 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

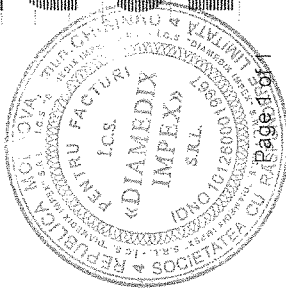
Version: 2.0

*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:  _____ **Date** 2016/08/12

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

Date
[YYYY-MM-DD]



EC DECLARATION OF CONFORMITY

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

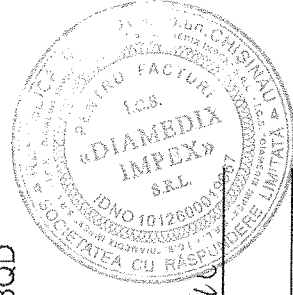
Cat. No. (REF) DF21

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

SIEMENS



Declaration of Conformity

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

Cat. No. (REF) DF77

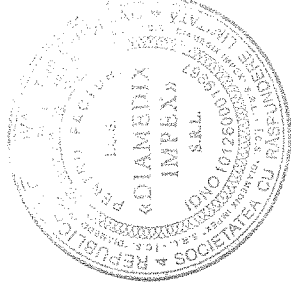
Manufacturer Address: Siemens Healthcare Diagnostics Inc.
500 GBC Drive
P.O. Box 6101
Newark, Delaware 19714-6101

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

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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® 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

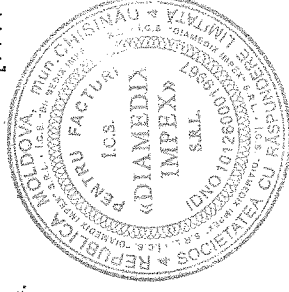
Version: 2.0

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Signature: *Yuk-Ting Lewis* 2017-09-11

Yuk-Ting Lewis
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® 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

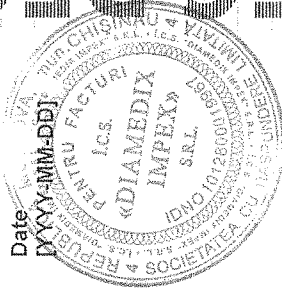
Version: 2.0

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Signature: 

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

Date: 2016/08/11



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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® Chemistry I Calibrator

Catalogue Number (REF): DC18C

Siemens Material Number (SMIN): 10716280

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Control Number: DoC_DM_CHEM I CAL_DC18C

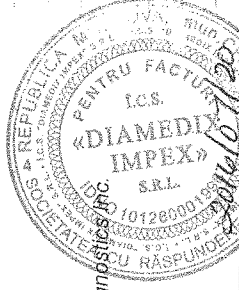
Version: 2.0

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Signature:

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

Date: [YYYY-MM-DD]



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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 Manufacturing Ltd.
Chapel Lane
Swords, Co. Dublin, Ireland

Product Name:

Dimension® Bilirubin Calibrator

Catalogue Number (REF):

DC167

Siemens Material Number (SMN):

10445013

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Control Number:

DoC_DM_TBI.DBI.CAL_DC167

Version:

3.0

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Signature:

**Carrio
Victor**

Digitally signed by Carrio Victor
DN: cn=Carrio Victor, o=Siemens
healthineers.com
Date: 2019.02.10 20:28:54 -05'00'

2019-02-10

Victor Carrio

**Sr. Manager Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
Newark, DE 19714**

Date

[YYYY-MM-DD]



