

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

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:

4.0

*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:

Carrio  
Victor

Digitally signed by Carrio Victor  
DN: cn=Carrio Victor, o=Siemens,  
email=carrio.victor@siemens-healthcare.com  
Date: 2019.02.10 21:01:13 +05'00'

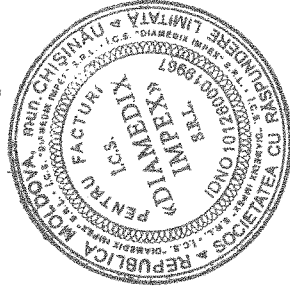
2019-02-10

Victor Carrio

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

Date

[YYYY-MM-DD]





**Note:** Product labeling may show Siemens Healthcare Diagnostics Inc. or Dade Behring Inc. during the labeling transition period.

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

# SIEMENS

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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:

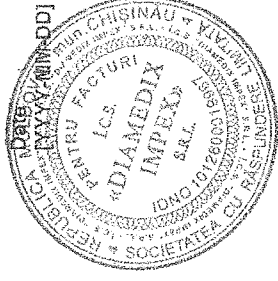
2.0

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*

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



SIEMENS

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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® 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:

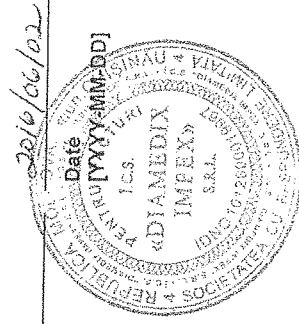
2.0

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



SIEMENS

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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® 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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This declaration supersedes any declaration issued previously for the same product.*

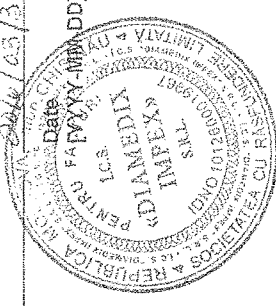
**Signature:**

*Rebecca S. Ayash*

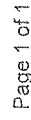
Rebecca S. Ayash  
Sr. Director Regulatory Affairs  
Siemens Healthcare Diagnostics Inc.  
Newark, DE 19714

Date

*2015/03/30*



# EC Declaration of Conformity



SIEMENS

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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® 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\_DBL\_DF125

**Version:**

2.0

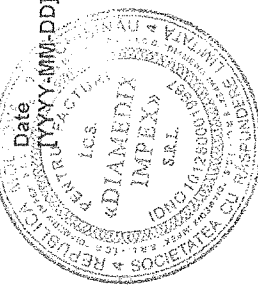
*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Inc.  
This declaration supersedes any declaration issued previously for the same product.*

Page 1 of 1

**Signature:**

*Rebecca S. Ayash*

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



Date  
2016/06/22

SIEMENS

EC Declaration of Conformity



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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® 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.  
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Signature:

*Rebecca S. Ayash*

Rebecca S. Ayash

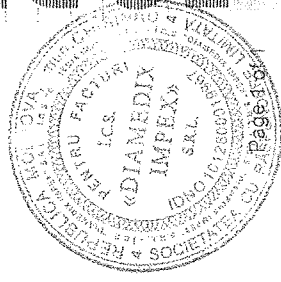
Sr. Director Regulatory Affairs  
Siemens Healthcare Diagnostics Inc.  
Newark, DE 19714

Date

[YYYY-MM-DD]

*2016/08/12*

Document No. DoC\_DM\_CRE2\_DF33B Ver. 2.0







Note: Product labeling may show Siemens Healthcare Diagnostics Inc. or Dade Behring Inc. during the labeling transition period.

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® 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:**

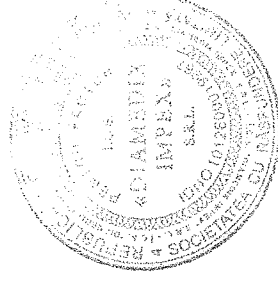
Siemens Healthcare Diagnostics Ltd.  
Sir William Siemens Sq.  
Frimley, Camberley, UK GU16 8QD

**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

# DECLARATION OF CONFORMITY



# DECLARATION OF CONFORMITY

2.0

[illegible]

# SIEMENS

## EC Declaration of Conformity



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**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® 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

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

*Yuk-Ting Lewis*

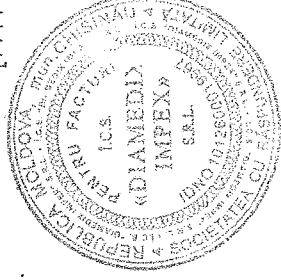
Yuk-Ting Lewis

Director Regulatory Affairs

Siemens Healthcare Diagnostics Inc.  
Newark, DE 19714

**Date**

[YYYY-MM-DD]



SIEMENS

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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® 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

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

*Rebecca S. Ayash*

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

Date  
2016/08/11



# 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® 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® Chemistry I Calibrator

**Catalogue Number (REF):**

DC18C

**Siemens Material Number (SMN):**

10716280

**Classification:**

General IVD

**Conformity Assessment Route:**

ANNEX III

**Document Control Number:**

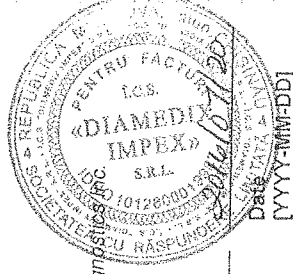
DoC\_DM\_CHEM I CAL\_DC18C

**Version:**

2.0

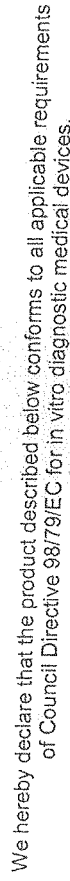
**Signature:**

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



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

Siemens Healthcare Diagnostics Manufacturing Ltd.  
Chapel Lane  
Swords, Co. Dublin, Ireland

Dimension® Bilirubin Calibrator

DC167

10445013

General IVD

ANEX III

DoC\_DM\_TBI.DBI\_CAL\_DC167

3.0

Carrio  
Victor

Digitally signed by Carrio Victor  
DN: cn=Carrio Victor, o=Siemens,  
email=carrio.v.m.carrio@siemens-  
healthineers.com  
Date: 2019.02.10 20:28:54 -0500

2019-02-10

Victor Cario

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

Date \_\_\_\_\_  
 Dwy \_\_\_\_\_

[XX-MM-DD]



Document No. DoC\_DM\_TBI.DBI\_CAL\_DC167 Ver. 3.0



SIEMENS

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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® Cholesterol Calibrator

**Catalogue Number (REF):**

DC16

**Siemens Material Number (SMN):**

10444998

**Classification:**

General IVD

**Conformity Assessment Route:**

ANNEX III

**Document Control Number:**

DoC\_DM\_CHOL\_CAL\_DC16

**Version:**

3.0

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

Carrio  
Victor

Digitally signed by Carrio Victor  
DN: cn=Carrio Victor o=Siemens,  
email=carrio.victor@siemens-  
healthcare.com, c=US  
Date: 2019.02.10 20:19:17 -0500

2019-02-10

Victor Carrio

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

Date

[YYYY-MM-DD]

