

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

Product Name:

Dimension® Alkaline Phosphatase Flex® reagent cartridge

Catalogue Number (REF):

DF150

Siemens Material Number (SMN):

10642445

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Control Number:

DoC\_DM\_ALPI\_DF150

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:

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 21:55:10 -05'00'

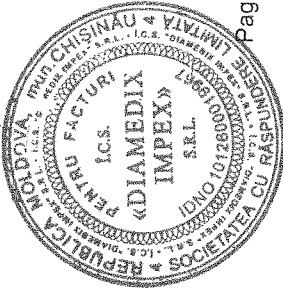
2019-02-10

Victor Carrio

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

Date

[YYYY-MM-DD]



SIEMENS

## EC Declaration of Conformity



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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:**

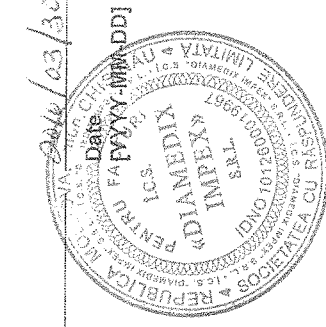
2.0

*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



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

Product Name:

Dimension® γ-Glutamyl Transferase Flex® reagent cartridge

Catalogue Number (REF):

DF45A

Siemens Material Number (SMN):

10444960

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Control Number:

DoC\_DM\_GGT\_DF45A

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:

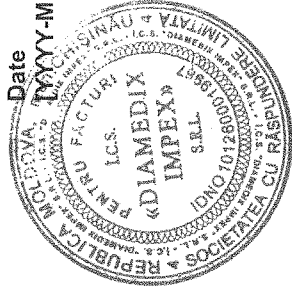
Carrio  
Victor

Digitally signed by Carrio Victor  
DN: cn=Carrio Victor, o=Siemens,  
email=Victor.M.Carrio@siemens-  
healthineers.com  
Date: 2019.02.10 19:42:46 +05'00'

2019-02-10

Victor Carrio

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



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

Product Name:

Dimension® Amylase Flex® reagent cartridge

Catalogue Number (REF):

DF17A

Siemens Material Number (SMN):

10444965

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Control Number:

DoC\_DM\_AMY\_DF17A

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:

Carrio  
Victor

Digitally signed by Carrio, Victor  
DN: cn=Carrio, Victor, o=Siemens,  
email=carrio.victor@siemens-  
healthcare.com  
Date: 2019.02.10 19:47:38 +05'00'

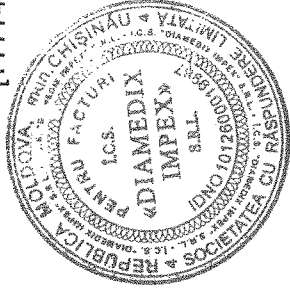
2019-02-10

Victor Carrio

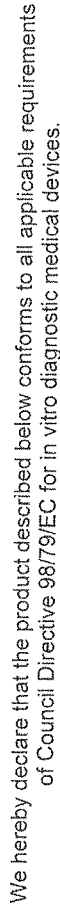
Sr. Manager Regulatory Affairs  
Siemens Healthcare Diagnostics Inc.  
Newark, DE 19714

Date

[YYYY-MM-DD]

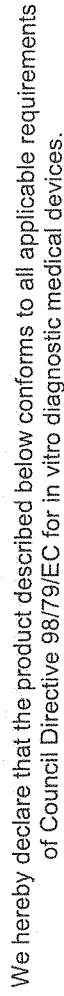


# EC Declaration of Conformity



Page 1 of 1

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Page 1 of 1

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Place of Manufacture:

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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® Lactate Dehydrogenase Flex® reagent cartridge

Catalogue Number (REF):

DF54

Siemens Material Number (SMN):

10284483

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Control Number:

DoC\_DM\_LDI\_DF54

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:

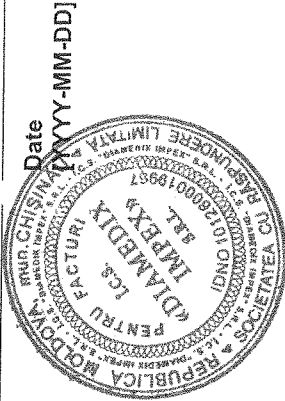
Carrio  
Victor

Digitally signed by Carrio Victor  
DN: cn=Carrio Victor, o=Siemens,  
email=carrio.victor@siemens-  
healthcare.com  
Date: 2019.02.10 18:00:38 +05'00'

2019-02-10

Victor Carrio

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



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Newark, DE, 19714, USA

EC Authorized Representative:

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

Product Name:

Dimension® Lipase Flex® reagent cartridge

Catalogue Number (REF):

DF56

Siemens Material Number (SMN):

10460277

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Control Number:

DoC\_DM\_LIPL\_DF56

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:

Carrio  
Victor

Digitally signed by Carrio Victor  
DN: cn=Carrio Victor, o=Siemens,  
email=victor.m.carrio@siemens-  
healthcare.com  
Date: 2019.02.10 21:14:09 +05'00'

2019-02-10

Victor Carrio  
Sr. Manager Regulatory Affairs  
Siemens Healthcare Diagnostics  
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® Albumin Flex® reagent cartridge

Catalogue Number (REF): DF13

Siemens Material Number (SMN): 10444975

Classification: General IVD

Conformity Assessment Route: ANNEX III

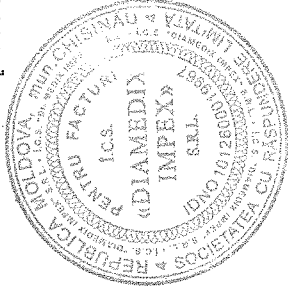
Document Control Number: DoC\_DM\_ALB\_DF13

Version: 2.0

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

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

Yuk-Ting Lewis  
Director Regulatory Affairs  
Siemens Healthcare Diagnostics Inc.  
Newark, DE 19714  
[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® Urea Nitrogen Flex® reagent cartridge (BUN)

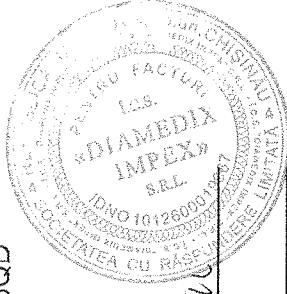
**Cat. No. (REF)** DF21

**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

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:

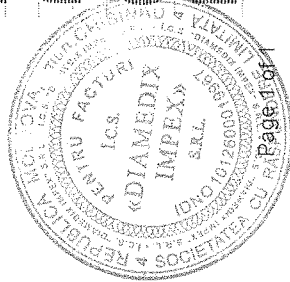
*Rebecca S. Ayash*

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

Date

[YYYY-MM-DD]

*2016/08/12*



# 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)

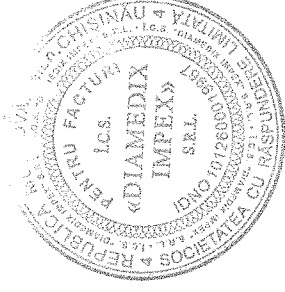
**Cat. No. (REF)** DF27

**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

# SIEMENS

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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® Total Bilirubin Flex® reagent cartridge

**Catalogue Number (REF):** DF167

**Siemens Material Number (SMN):** 10444957

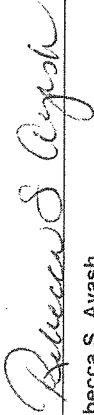
**Classification:** General IVD

**Conformity Assessment Route:** ANNEX III

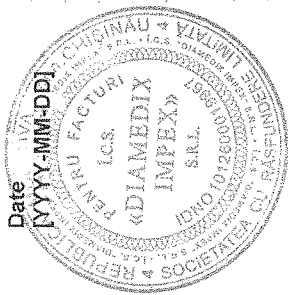
**Document Control Number:** DoC\_DM\_TBI\_DF167

**Version:** 2.0

*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:** 2016/10/27





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Siemens Healthcare Diagnostics Inc.  
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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

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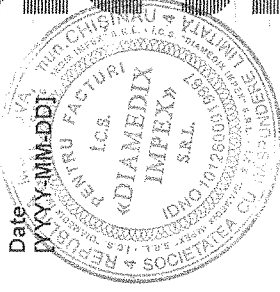
Signature:

Queen Elizabeth

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

2016/09/11

Date \_\_\_\_\_



Document No. DoC DM GLUC DF40 Ver. 2.0

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

Product Name:

Dimension® Automated HDL Cholesterol Flex® reagent cartridge

Catalogue Number (REF):

DF48B

Siemens Material Number (SMN):

10464332

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Control Number:

DoC\_DM\_AHDL\_DF48B

Version:

3.0

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Signature:

Carrio  
Victor

Digitally signed by Carrio Victor  
DN: cn=Carrio Victor, o=Siemens,  
email=carrio.m.carrio@siemens-  
healthcare.com  
Date: 2019.02.10 11:25:17 +05'00'

2019-02-10

Victor Carrio

Sr. Manager Regulatory Affairs  
Siemens Healthcare Diagnostics Inc.  
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 Manufacturing Ltd.  
Chapel Lane  
Swords, Co. Dublin, Ireland

Product Name:

Dimension® Automated LDL Flex® reagent cartridge

Catalogue Number (REF):

DF131

Siemens Material Number (SMN):

10444890

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Control Number:

DoC\_DM\_ALDL\_DF131

Version:

3.0

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

Signature:

Carrio  
Victor

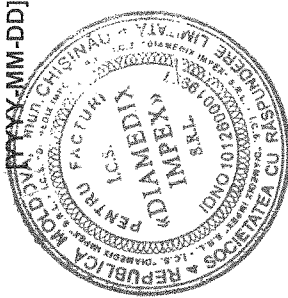
Digitally signed by Carrio Victor  
DN: cn=Carrio Victor, o=Siemens,  
email=victor.m.carrio@siemens-  
healthcare.com  
Date: 2019.02.10 18:20:45 +05'00'

2019-02-10

Victor Carrio

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

Date



# SENSES



## 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

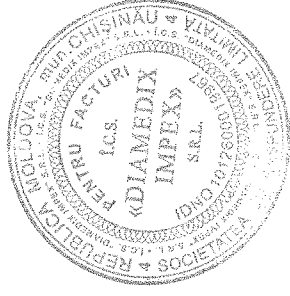
Print Julie L. Feaster

Regulatory Affairs & Quality Systems

Representative

**Siemens Healthcare Diagnostics Inc.**

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



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® 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

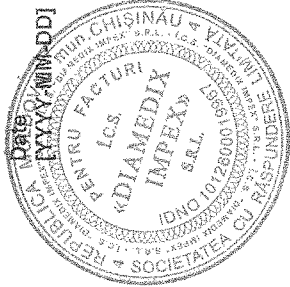
This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Inc.  
This declaration supersedes any declaration issued previously for the same product.

Signature:

*Rebecca S. Ayash*

2015/10/27

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





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.

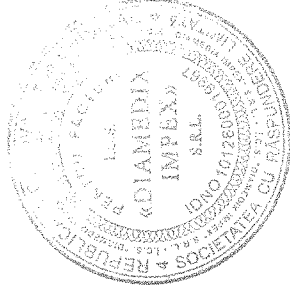
Note: Product labelling may show Siemens Healthcare Diagnostics Inc. or Dade Behring Inc. during the labelling transition period.

|                       |                                                                                                 |
|-----------------------|-------------------------------------------------------------------------------------------------|
| Cat. No. (REF)        | DF77                                                                                            |
| Manufacturer Address: | Siemens Healthcare Diagnostics<br>500 GBC Drive<br>P.O. Box 6101<br>Newark, Delaware 19714-6101 |

Date: 2008-07-01

Authorization: Signature Julie L. Feaster

Print Julie L. Feaster  
Regulatory Affairs & Quality Systems  
Representative



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

Product Name:

Dimension® Calcium Flex® reagent cartridge

Catalogue Number (REF):

DF23A

Siemens Material Number (SMN):

10444949

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Control Number:

DoC\_DM\_CA\_DF23A

Version:

3.0

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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=victor.m.carrio@siemens-  
healthineers.com  
Date: 2019.02.10 19:36:45 +05'00'

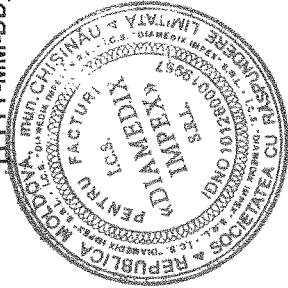
2019-02-10

Victor Carrio

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

Date

YYYY-MM-DDJ



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

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:

3.0

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Signature:

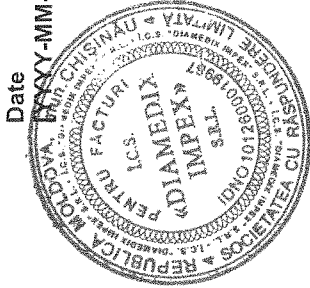
Carrio  
Victor

Digitally signed by Carrio Victor  
DN: cn=Carrio Victor, o=Siemens,  
email=carrio.victor@siemens-healthineers.com  
Date: 2019.02.10 19:33:27 +0500

2019-02-10

Victor Carrio

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



Date

2019-02-10

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

Product Name:

Dimension® Magnesium Flex® reagent cartridge

Catalogue Number (REF):

DF57

Siemens Material Number (SMN):

10444963

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Control Number:

DoC\_DM\_MG\_DF57

Version:

3.0

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Signature:

Carrio  
Victor

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DN: cn=Carrio Victor, o=Siemens,  
email=victor.m.carrio@siemens-  
healthcare.com  
Date: 2019.02.10 19:45:24 +05'00'

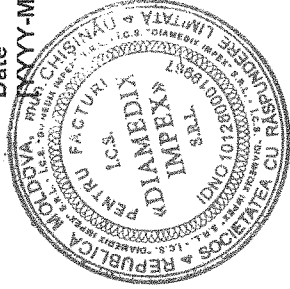
2019-02-10

Victor Carrio

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

Date

2019-02-10



EC Declaration of Conformity



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

Product Name:

Dimension® Phosphorus Flex® reagent cartridge

Catalogue Number (REF):

DF61A

Siemens Material Number (SMN):

10720277

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Control Number:

DoC\_DM\_PHOS\_DF61A

Version:

3.0

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Signature:

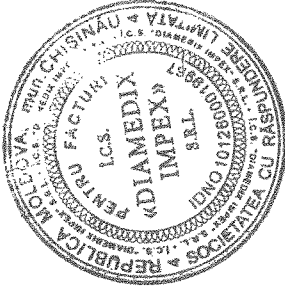
Carrio  
Victor

Digitally signed by Carrio Victor  
DN: cn=Carrio Victor, o=Siemens,  
email=carrio.victor@siemens-  
healthcare.com  
Date: 2019.02.10 22:08:25 +05'00'

2019-02-10

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

Date  
[YYYY-MM-DD]



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® 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

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Signature:

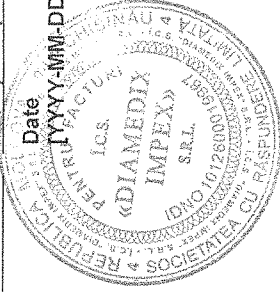
*Rebecca S. Ayash*

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

Date

2016/06/22

YYYY-MM-DD]



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

Product Name:

Dimension® C-Reactive Protein Extended Range Flex® reagent cartridge

Catalogue Number (REF):

DF34

Siemens Material Number (SMN):

10444903

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Control Number:

DoC\_DM\_RCRP\_DF34

Version:

3.0

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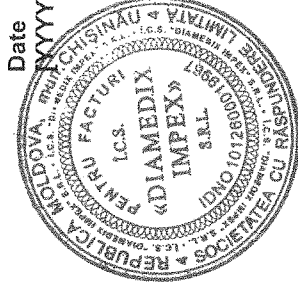
Carrio  
Victor

Digitally signed by Carrio Victor  
DN: cn=Carrio Victor, o=Siemens,  
email=victor.m.carrio@siemens-  
healthcare.com  
Date: 2019.02.10 19:35:48 +05'00'

2019-02-10

Victor Carrio

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



Date

YYYY-MM-DDJ

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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

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Victor

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DN: cn=Carrio Victor, o=Siemens,  
email=victor.m.carrio@siemens-  
healthineers.com  
Date: 2019.02.10 21:01:13 +0500'

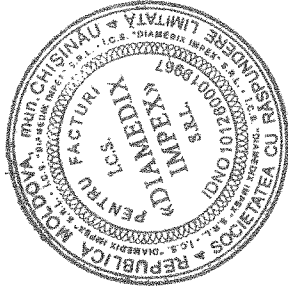
2019-02-10

Victor Carrio

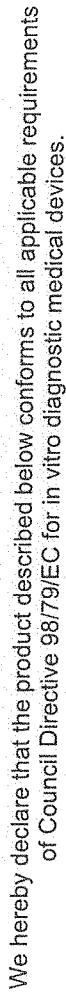
Sr. Manager Regulatory Affairs  
Siemens Healthcare Diagnostics, Inc.  
Newark, DE 19714

Date

[YYYY-MM-DD]



# EC Declaration of Conformity



Page 1 of 2

EC Declaration of Conformity



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Legal Manufacturer:

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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® 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:

3.0

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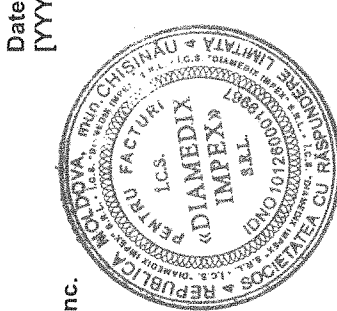
Carrio  
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DN: cn=Carrio Victor, o=Siemens,  
email=carrio.m.carrio@siemens-  
healthcare.com  
Date: 2019.02.19 17:10:25 +05'00'

2019-02-19

Victor Carrio

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



Date

[YYYY-MM-DD]