

# 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, Malistop 514, P.O. Box 6101  
Newark, DE, 19714, USA

**Place of Manufacture:** Siemens Healthcare Diagnostics Inc.  
500 GBC Drive, Malistop 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

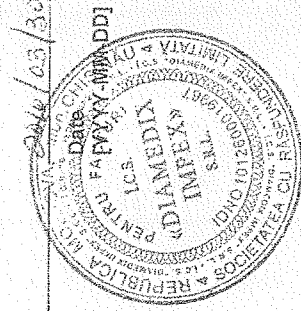
*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Inc.  
This declaration supersedes any declaration issued previously for the same product.*

Product Code

Signature:

*Rebecca S. Ayash*

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 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

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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-  
healthcareers.com  
Date: 2019.02.10 19:47:38 -05'00'

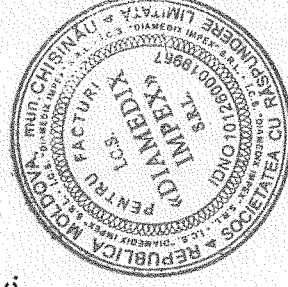
2019-02-10

**Victor Carrio**

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

**Date**

**[YYYY-MM-DD]**



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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® Aspartate Aminotransferase Flex® reagent cartridge

**Catalogue Number (REF):** DF41A

**Siemens Material Number (SMN):** 10444959

**Classification:** General IVD

**Conformity Assessment Route:** ANNEX III

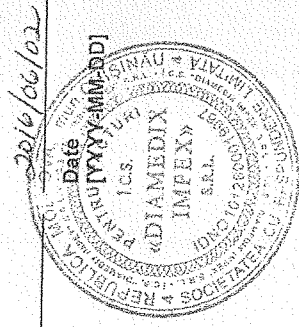
**Document Control Number:** DoC\_DM\_AST (GOT)\_DF41A

**Version:** 2.0

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**Signature:**

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® Creatine Kinase MB Flex® reagent cartridge

**Catalogue Number (REF):**

DF32

**Siemens Material Number (SMN):**

10464510

**Classification:**

General IVD

**Conformity Assessment Route:**

ANNEX III

**Document Control Number:**

DoC\_DM\_MBI\_DF32

**Version:**

3.0

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**Signature:**

**Carrio  
Victor**

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DN: cn=Carrio Victor, o=Siemens,  
email=carrio.victor@siemens-  
healthcare.com  
Date: 2019.02.10 21:28:37 +05'00'

2019-02-10

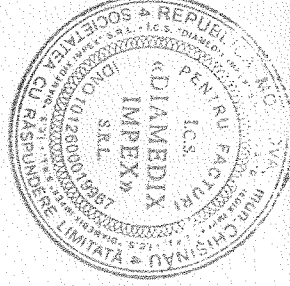
**Victor Carrio**

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

**Date**

**[YYYY-MM-DD]**

Document No. DoC\_DM\_MBI\_DF32 Ver. 3.0





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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® 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

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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 18:00:38 -0500

2019-02-10

**Product Name:**

Dimension® Lactate Dehydrogenase Flex® reagent cartridge

Dimension® Lactate Dehydrogenase Flex® reagent cartridge

Dimension® Lactate Dehydrogenase Flex® reagent cartridge

**Victor Carrio**

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

**Date**

**[YYYY-MM-DD]**

Document No. DoC\_DM\_LDI\_DF54 Ver. 3.0



# 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

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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

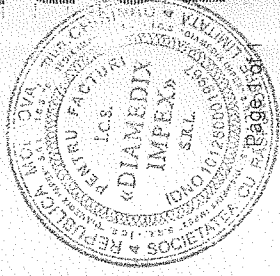
**Version:** 2.0

*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

**Date:** [YYYY-MM-DD]  
Rebecca S. Ayash  
Sr. Director Regulatory Affairs  
Siemens Healthcare Diagnostics Inc.  
Newark, DE 19714

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







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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® 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**

2016/10/27



EC DECLARATION OF CONFORMITY

# 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

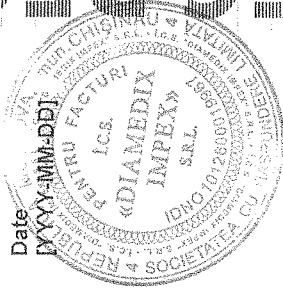
**Version:** 2.0

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**Signature:** 

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

Date: 2016/08/11



DECLARATION OF CONFORMITY

# 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® 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

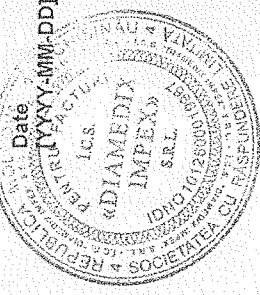
**Version:** 2.0

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Page 1 of 1

Signature:

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



Document No. DoC\_DM\_DBI\_DF125 Ver. 2.0

Page 1 of 1

EC DECLARATION OF CONFORMITY

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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 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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**Signature:**

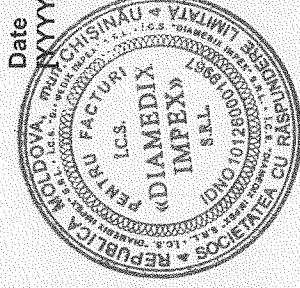
Carrio  
Victor

Digitally signed by Carrio Victor  
DN: cn=Carrio Victor, o=Siemens,  
email=carrio.victor@siemens-healthineers.com  
Date: 2019.02.10 16:35:48 +05'00'

2019-02-10

**Victor Carrio**

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



**Date**

2019-02-10

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

**Product Name:**

Dimension® Transferrin Flex® reagent cartridge

**Catalogue Number (REF):**

DF103

**Siemens Material Number (SMN):**

10444985

**Classification:**

General IVD

**Conformity Assessment Route:**

ANNEX III

**Document Control Number:**

DoC\_DM\_TRNF\_DF103

**Version:**

3.0



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**Signature:**

**Carrio  
Victor**

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healthcare.com  
Date: 2019.02.10 20:04:01 +05'00'

2019-02-10

**Victor Carrio**

**Sr. Manager 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® Chemistry I Calibrator

**Catalogue Number (REF):**

DC18C

**Siemens Material Number (SMN):**

10716280

**Classification:**

General IVD

**EC Authorized Rep**

**Conformity Assessment Route:**

ANNEX III

**Product Name**

**Document Control Number:**

DoC\_DM\_CHEM I CAL\_DC18C

**Version:**

3.0

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EC Authorized Rep

**Signature:**

**Carrio  
Victor**

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DN: cn=Carrio Victor, o=Siemens,  
email=carrio.victor@siemens-  
healthcare.com  
Date: 2019.02.19 17:10:25 -0500

2019-02-19

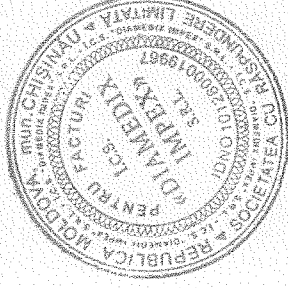
Victor Carrio

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

Date

[YYYY-MM-DD]

Document No. DoC\_DM\_CHEM I CAL\_DC18C Ver. 3.0



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Newark, DE, 19714, USA

**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® Alkaline Phosphatase Calibrator

**Catalogue Number (REF):**

DC150

**Siemens Material Number (SMN):**

10714028

**Classification:**

General IVD

**Conformity Assessment Route:**

ANNEX III

**Document Control Number:**

DoC\_DM\_ALPI\_CAL\_DC150

**Version:**

3.0

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**Signature:**

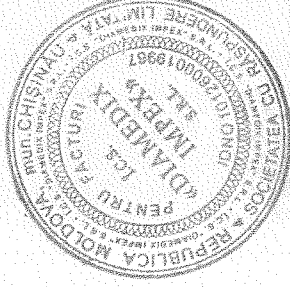
**Carrio  
Victor**

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healthcare.com  
Date: 2019.02.10 22:04:52 -0500

2019-02-10

**Victor Carrio  
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Newark, DE 19714**

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Document No. DoC\_DM\_ALPI\_CAL\_DC150 Ver. 3.0

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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:**

Fisher Diagnostics  
A division of Fisher Scientific Company, LLC  
A part of Thermo Fisher Scientific, Inc.  
8365 Valley Pike  
Middletown, VA 22645, USA

**EC Authorized Representative:**

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

**Product Name:**

Dimension® Chemistry II Calibrator

**Catalogue Number (REF):**

DC20

**Siemens Material Number (SMN):**

10444997

**Classification:**

General IVD

**Conformity Assessment Route:**

ANNEX III

**Document Control Number:**

DoC\_DM\_CHEM II CAL\_DC20

**Version:**

4.0

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

**Carrio  
Victor**

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2019-02-10

**Victor Carrio**

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

**Product Name:**

Dimension® Total Protein/Albumin Calibrator

**Catalogue Number (REF):**

DC31

**Siemens Material Number (SMN):**

10444993

**Classification:**

General IVD

**Conformity Assessment Route:**

ANNEX III

**Document Control Number:**

DoC\_DM\_TP ALB CAL\_DC31

**Version:**

3.0

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**Signature:**

Carrio  
Victor

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healthcare.com  
Date: 2019.02.10 20:13:20 +05'00'

2019-02-10

**Victor Carrio**

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

**Date**  
**[YYYY-MM-DD]**

Document No. DoC\_DM\_TP ALB CAL\_DC31 Ver. 3.0





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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® CKI/MBI Calibrator

**Catalogue Number (REF):**

DC32

**Siemens Material Number (SMN):**

10464508

**Classification:**

General IVD

**Conformity Assessment Route:**

ANNEX III

**Document Control Number:**

DoC\_DM\_CKI.MBI CAL\_DC32

**Version:**

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email=carrio.victor@siemens-healthineers.com  
Date: 2019.02.10 21:27:33 +05'00'

2019-02-10

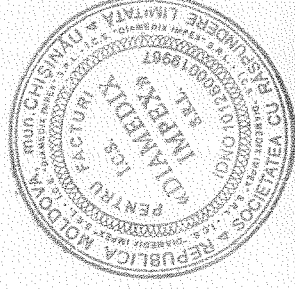
**Victor Carrio**

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

**Date**

[YYYY-MM-DD]

Document No. DoC\_DM\_CKI.MBI CAL\_DC32 Ver. 3.0







## 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:**

Fisher Diagnostics  
A division of Fisher Scientific Company, LLC  
A part of Thermo Fisher Scientific, Inc.  
8365 Valley Pike  
Middletown, VA 22645, USA

**EC Authorized Representative:**

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

**Product Name:**

Dimension® Iron Calibrator

**Catalogue Number (REF):**

DC85

**Siemens Material Number (SMN):**

10445010

**Classification:**

General IVD

**Conformity Assessment Route:**

ANNEX III

**Document Control Number:**

DoC\_DM\_IRON\_CAL\_DC85

**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-  
healthineers.com  
Date: 2019.02.13 11:04:40 -05'00'

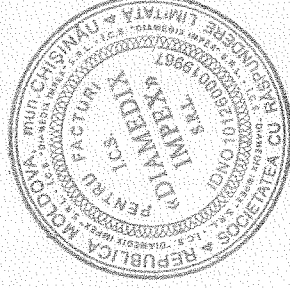
2019-02-13

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

**Date**

**[YYYY-MM-DD]**

Document No. DoC\_DM\_IRON\_CAL\_DC85 Ver. 3.0



## 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® 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. 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=Moldova  
Date: 2019.02.10 20:18:17 +0500

2019-02-10

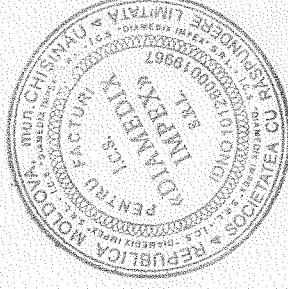
**Victor Carrio**

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

**Date**

**[YYYY-MM-DD]**

Document No. DoC\_DM\_CHOL\_CAL\_DC16 Ver. 3.0



## 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® Revised C-Reactive Protein Calibrator

**Catalogue Number (REF):**

DC34

**Siemens Material Number (SMN):**

10445026

**Classification:**

General IVD

**Conformity Assessment Route:**

ANNEX III

**Document Control Number:**

DoC\_DM\_RCRP CAL\_DC34

**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**

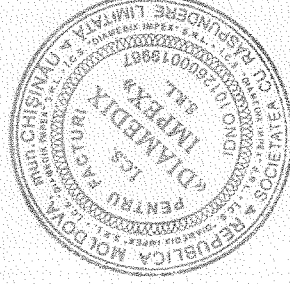
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DN: cn=Carrio Victor, o=Siemens,  
email=carrio.victor@siemens-  
healthineers.com  
Date: 2019.02.10 20:45:04 +05'00'

2019-02-10

**Victor Carrio**

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

**Date  
[YYYY-MM-DD]**



## EC Declaration of Conformity



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® AHDL Calibrator

**Catalogue Number (REF):**

DC48B

**Siemens Material Number (SMN):**

10464328

**Classification:**

General IVD

**Conformity Assessment Route:**

ANNEX III

**Document Control Number:**

DoC\_DM\_AHDL\_CAL\_DC48B

**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 21:20:59 +05'00'

2019-02-10

**Victor Carrio**

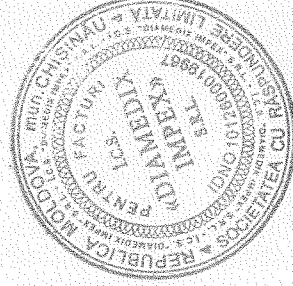
**Sr. Manager Regulatory Affairs**

**Siemens Healthcare Diagnostics**

**Newark, DE 19714**

**Date**

**[YYYY-MM-DD]**





# 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.*

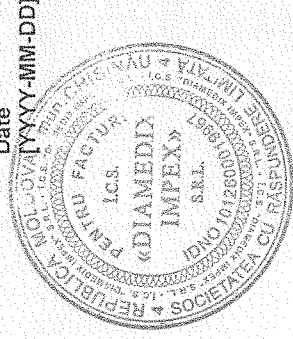
**Signature:**

*Rebecca S. Ayash*

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

**Date**

*2016/08/05*



EC DECLARATION OF CONFORMITY