

# 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 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.*

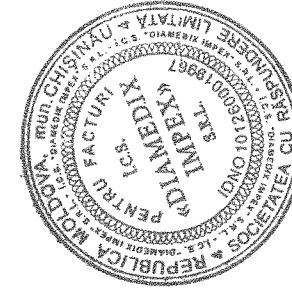
**Signature:**

Carrio  
Victor

2019-02-10

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

Victor Carrio  
Sr. Manager 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 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:**

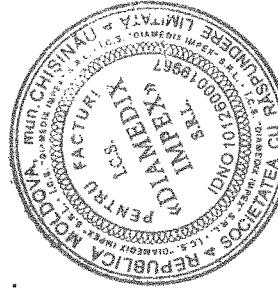
3.0

*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.*

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

**Signature:** \_\_\_\_\_  
**Date:** \_\_\_\_\_  
**[YYYY-MM-DD]**

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



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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® Aspartate Aminotransferase Flex® reagent cartridge

**Catalogue Number (REF):**

DF41A

**Siemens Material Number (SMN):**

10444959

**Classification:**

General IV/D

**Conformity Assessment Route:**

ANNEX III

**Document Control Number:**

DoC\_DM\_AST (GOT)\_DF41A

**Version:**

3.0

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

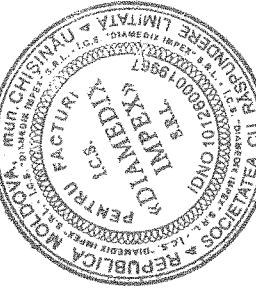
**Signature:**

Carrio  
Victor

2019-02-10

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

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® 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:**

3.0

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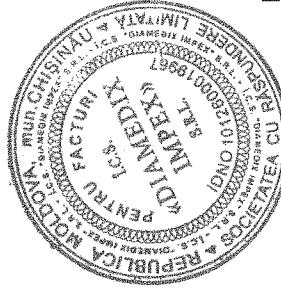
**Signature:**

Carrio  
Victor

2019-02-10

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

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



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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® Urea Nitrogen Flex® reagent cartridge

**Catalogue Number (REF):**

DF21

**Siemens Material Number (SMN):**

10444969

**Classification:**

General IVD

**Conformity Assessment Route:**

ANNEX III

**Document Control Number:**

DoC\_DM\_BUN\_DF21

**Version:**

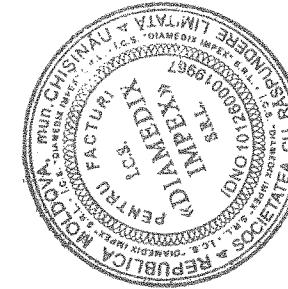
3.0

*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,  
emailcarrio.victor@siemens-healthineers.com  
Date: 2019.02.10 19:50:06 -05'00'

**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® 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:**

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:**

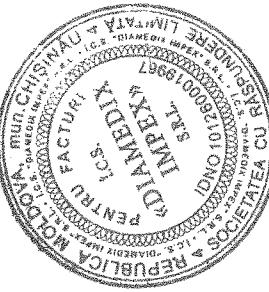
Carrio  
Victor

Digitally signed by Carrio Victor  
DN: cn=Carrio Victor, o=Siemens,  
email=carrio.m.carro@siemens-  
healthcare.com  
Date: 2019.02.10 22:09:31 +05'00'

**Date:**

2019-02-10  
[YYYY-MM-DD]

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® Glucose Flex® reagent cartridge

**Catalogue Number (REF):**

DF40

**Siemens Material Number (SMN):**

10444971

**Classification:**

General IVD

**Conformity Assessment Route:**

ANNEX III

**Document Control Number:**

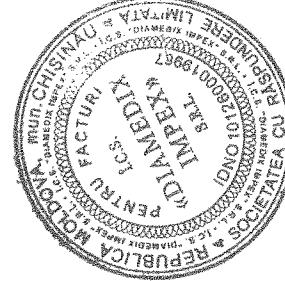
DoC\_DM\_GLUC\_DF40

**Version:**

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.*

<b>Signature:</b>	<b>Carrio Victor</b>	<b>Date:</b>
	Victor Carrio Sr. Manager Regulatory Affairs Siemens Healthcare Diagnostics Inc. Newark, DE 19714	2019-02-10 [YYYY-MM-DD]



SIEMENS  
ECD

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

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

Product Name:

Catalogue Number (REF):

Siemens Material Number (SMN):

Classification:

Conformity Assessment Route: ANNEX III

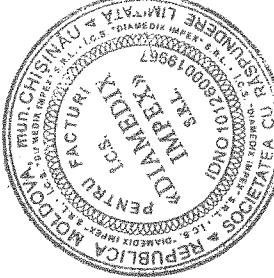
Document Control Number: Doc DM TB DE73

30 Version:

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:** Victor Carrio  
Victor Carrio  
Siemens Healthcare Diagnostics Inc.  
Sr. Manager Regulatory Affairs  
Newark DE 19714  
Digitally signed by Carrio  
DN: cn=Victor.o=SiemensHealthcare  
emailAddress=carrio@siemens-healthcare.com  
Date: 2019-02-10 19:57:29

Date 11-11-2014



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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

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

Carrio  
Victor

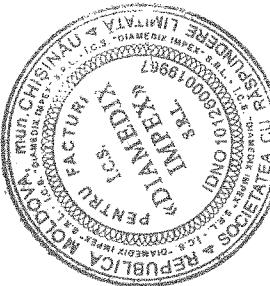
Digitally signed by Carrio Victor,  
DN: cn=Carro Victor, o=Siemens,  
email: ricm\_carro@siemens-healthineers.com  
Date: 2019/02/19 17:02:25 -05'00'

2019-02-19

Victor Carrio

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

Date  
[YYYY-MM-DD]



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**Legal Manufacturer:**

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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:**

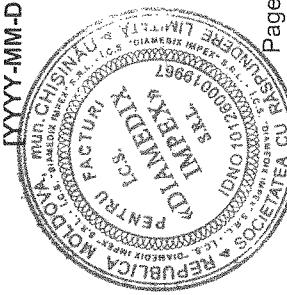
Carrio  
Victor

Digital signature by Carrio Victor  
DN: crn:Carro Victor, o:Siemens-  
healthcare, email:carro.m.carro@siemens-  
healthcare.com  
Date: 2019-02-10 20:17:57-05'00

2019-02-10  
[XXXX-MM-DD]

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

Date  
[XXXX-MM-DD]



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

**Place of Manufacture:**

Nypro Mebane  
1018 Corporate Park Drive  
Mebane, North Carolina, 27302, USA  
  
Currier Plastics, Inc.  
101 Columbus Street  
Auburn, New York, 13021, USA

**EC Authorized Representative:**

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

**Product Name:**

Dimension®/ Dimension Vista® Sample Cups

**Catalogue Number (REF):**

DSC4

**Siemens Material Number (SMN):**

10445041

**Classification:**

General IVD

**Conformity Assessment Route:**

ANNEX III

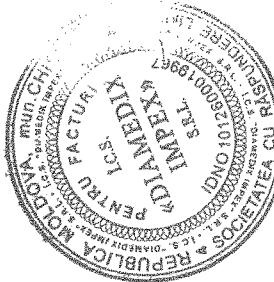
**Document Control Number:**

DoC\_DM\_DV\_Sample Cups\_DSC4

**Version:**

5.0

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

## **EC Declaration of Conformity**

Ryan Sherrie

Signature:

Sherrie Ryan  
Director Regulatory Affairs  
Siemens Healthcare Diagnos-  
tics  
Newark, DE 19714

Date [MMYY-MM-DD]

Digitally signed by Ryan Sherrie  
DN: serialNumber=2002ZFR, givenName=Sherrie,  
sn=Ryan, o=Siemens, cn=Ryan Sherrie  
Reason: I am approving this document  
Date: 2020.11.09 10:03:23 -05'00'

A circular stamp with the following text:  
MINISTERSTVO Vnutrjennix Sistem  
RFSR  
MOSKVA  
PENITENCIJNAYA SISTEMA  
"DIANEKSI"  
FACTURA  
LCS  
IMPEX  
SAV  
SOCIETATEA CU RSP  
DNI 10.10.2005

# SIEMENS

## EC Declaration of Conformity

CE

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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

This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Inc.  
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Digitally signed by Carrio Victor  
DN: cn=Carrio Victor, o=Siemens,  
email=carrio.m.carrio@siemens-  
healthcare.com  
Date: 2019 02 10 21:01:13 +05'00'

**Signature:**

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

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

2019-02-10

