

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



DECLARATION OF CONFORMITY

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

Date: 2016/08/05

Date [YYYY-MM-DD]



EC DECLARATION OF CONFORMITY

# 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

## 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 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



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 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

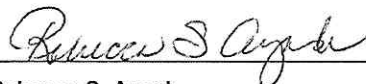
**Conformity Assessment Route:** ANNEX III

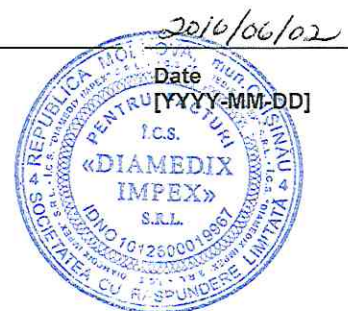
**Document Control Number:** DoC\_DM\_AST (GOT)\_DF41A

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



EC DECLARATION OF CONFORMITY

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



EC DECLARATION OF CONFORMITY

# 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 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

2016/10/27

Date  
[YYYY-MM-DD]



EC DECLARATION OF CONFORMITY

## 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® 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=victor.m.carrio@siemens-  
healthineers.com  
Date: 2019.02.10 22:09:31 -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® 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,  
email=victor.m.carrio@siemens-  
healthineers.com  
Date: 2019.02.10 19:50:06 -05'00'

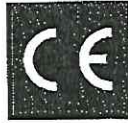
**Date** 2019-02-10  
[YYYY-MM-DD]

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



DECLARATION OF CONFORMITY

# 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.

<b>Product:</b>	Dimension® Uric Acid Flex® reagent cartridge (URCA)
<b>Cat. No. (REF)</b>	DF77
<b>Manufacturer Address:</b>	Siemens Healthcare Diagnostics Inc. 500 GBC Drive P.O. Box 6101 Newark, Delaware 19714-6101
<b>EU Authorized Representative:</b>	Siemens Healthcare Diagnostics Ltd. Sir William Siemens Sq. Frimley, Camberley, UK GU16 8QD
<b>Date:</b>	2008-07-01
<b>Authorization:</b>	<u>Signature</u> <u>Julie L. Feaster</u> <u>Print</u> Julie L. Feaster Regulatory Affairs & Quality Systems Representative

Siemens Healthcare Diagnostics Inc.

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



## 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

*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 19:33:27 +05'00' **2019-02-10**

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

**Date**  
**YY-MM-DD]**



DECLARATION OF CONFORMITY

# 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 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.  
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: 2016/08/11



EC DECLARATION OF CONFORMITY

