

SIEMENS
EC Declaration of C

EC Declaration of Conformity

CE

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 5114, 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: Dimension® Alkaline Phosphatase Flex® reagent cartridge

Catalogue Number (REF):

Siemens Material Number (SWMN): 106424

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20

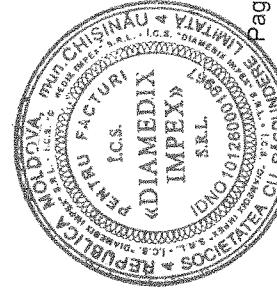
This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Inc.

**Carrio
Victor**
Digitally signed by Carrio Victor
DN: cn=Carrio Victor, o=Siemens,
email=vcitor.m.carro@siemens-
healthineers.com
Date: 2019.02.10 21:56:10 -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_ALP1_DF150 Ver. 3.0

SIEGENS

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

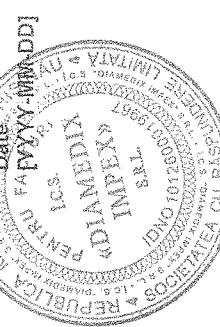
Version:

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



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 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

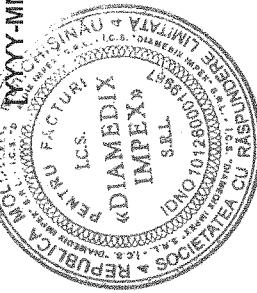
2019-02-10

Victor Carrio

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

Date

[MM-YY-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® 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

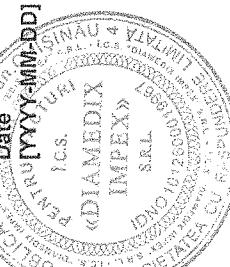
This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Inc.
This declaration supersedes any declaration issued previously for the same product.

Signature:

Rebecca S. Ayash

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

2016/06/02



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, Maitstop 514, P.O. Box 6101
Newark, DE, 19714, USA

Place of Manufacture:

Siemens Healthcare Diagnostics Inc.
500 GBC Drive, Maitstop 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 Vista® Mass CKMB Isoenzyme Calibrator

Catalogue Number (REF):

KC672

Siemens Material Number (SMN):

10445195

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Control Number:

DoC_DV_MMB CAL_KC672

Version:

3.0

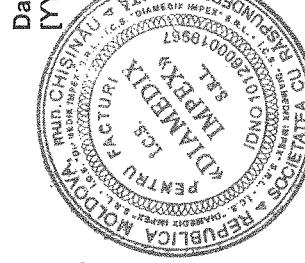
*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Inc.
This declaration supersedes any declaration issued previously for the same product.*

Signature:

Ryan Sherrie

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

Date
[YYYY-MM-DD]



Digitally signed by Ryan Sherrie
DN: serialNumber=20026ZFR, givenName=Sherrie,
sn=Ryan, o=Siemens, cn=Ryan Sherrie
Date: 2019.02.12 23:54:05 -05'00'

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® 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-
healthcare.com
Date: 2019.02.10 18:00:38 -05'00'

Date:
[REDACTED]

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 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

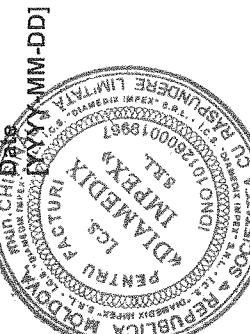
This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Inc.

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

Signature:

Carrio
Victor
2019-02-10

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



SIEMENS

EC Declaration of Conformity



We hereby declare that the product described below conforms to all applicable requirements
of Council Directive 93/42/EEC 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® 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

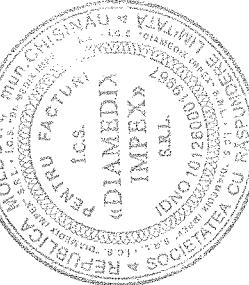
This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Inc.
This declaration supersedes any declaration issued previously for the same product.

Signature:

Yuk-Ting Lewis
Director Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
Newark, DE 19714

2017-07-07

Date
[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

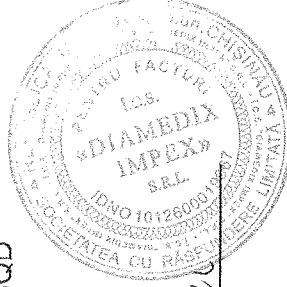
EU Authorized Representative:

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

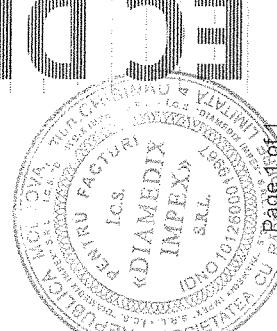
This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Inc.
This declaration supersedes any declaration issued previously for the same product.

Signature:

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

2016/10/12

Date
[YYYY-MM-DD]



Document No. DoC_DM_CRE2_DF33B Ver. 2.0

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® 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

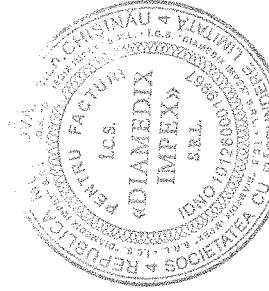
EU Authorized Representative:

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

Date: 2008-07-01

Authorization:

Julie L. Feaster
Signature _____
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® 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

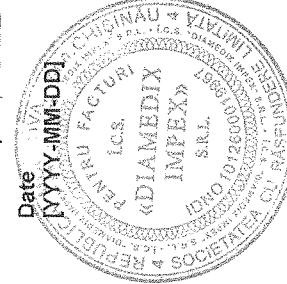
This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Inc.

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

2014/10/27



SIEMENS

EC Declaration of Conformity



We hereby declare that the product described below conforms to all applicable requirements of Council Directive 93/42/EEC 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

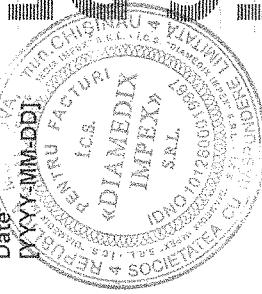
Version:

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



Document No. DoC_DM_GLUC_DF40 Ver. 2.0

Page 1 of 1

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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

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=vcarrio.m.carrio@siemens-
healthcare.com
Date: 2019.02.10 21:25:17-05'00

Date	2019-02-10
Carrio Victor	
Victor Carrio Sr. Manager Regulatory Affairs Siemens Healthcare Diagnostics Inc. Newark, DE 19714	

Document No. DoC_DM_AHDL_DF48B Ver. 3.0

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 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:

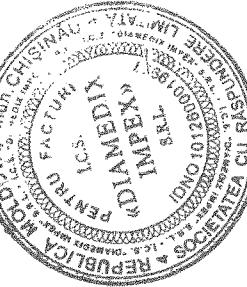
Carrio
Victor

2019-02-10

Date

[CE MARK-MM-DD]

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



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:

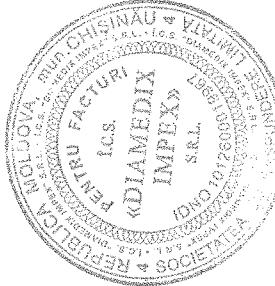
Siemens Healthcare Diagnostics Ltd.
Sir William Siemens Sq.
Frimley, Camberley, UK GU16 8QD

Date: 2008-07-01

Authorization:

Julie L. Feaster
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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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

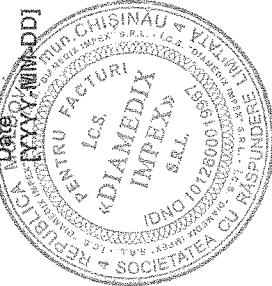
Version:

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:

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



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:**

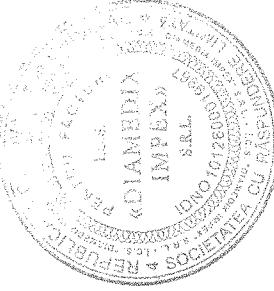
Siemens Healthcare Diagnostics Ltd.
Sir William Siemens Sq.
Frimley, Camberley, UK GU16 8QD

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

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

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:

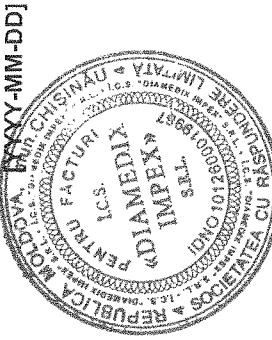
Carrio
Victor

2019-02-10

Date

[CEX-MM-DD]

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



Document No. Doc_DM_IRON_DF85 Ver. 3.0

Page 1 of 1

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® 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

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.

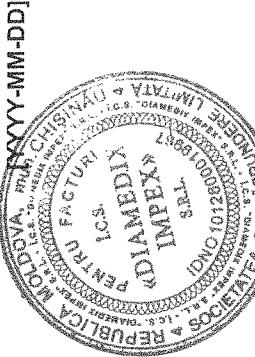
Signature:

Carrio
Victor

DN: cn=Carro Victor, o=Siemens,
email:carro.m.carro@siemens-
healthineers.com
Date: 2019.02.10 19:45:24 +05'00'

2019-02-10

Date



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

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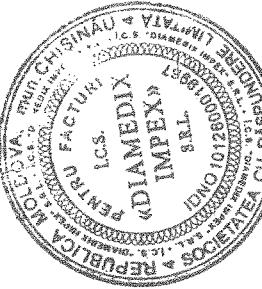
This declaration supersedes any declaration issued previously for the same product.

Signature:

Carrio
Victor

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

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



Document No. DoC_DM_PHOS_DF61A Ver. 3.0

Page 1 of 1

SIEMENS **EC Declaration of Conformity**

EC Declaration of Conformity

A black rectangular box containing the white CE mark, which consists of two interlocking circles.

We hereby declare that the product described below conforms to all applicable requirements of Council Directive 93/89/EEC 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® Direct Bilirubin

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Conformity Asses

ANNEX

D8C_DM_DB1_DF | 23

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:

Bethel S. Amory

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

A circular stamp with the text "DIAMEDIX IMPEX S.R.L." around the perimeter and "15.05.1997" in the center.

Document No. DocC_DM_DB1_DF125 Ver. 2.0

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 Manufacturers

Siemens Healthcare Diagnostics Inc.
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

EC Authorized Representative:
Siemens Healthcare Diagnostics Manufacturing Ltd.
Chapel Lane
Swords, Co. Dublin, Ireland

Product Name:

Catalogue Number (REF):

Siemens Material Number (SMN): 10444903

Classification:

Community Assessment Route:

Document Control Number: DoC_DM_RCRP_DF34

3.0
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: 
Carrio Victor
Digitally signed by Carrio Victor
Date: 2019-02-18T18:35:48-05:00
[digitalsignature.com](https://www.digitalsignature.com)

Carrio Victor
Digitally signed by Carrio Victor
DN: cn=Carrio Victor, o=Siemens,
email=Victor.m.carriov@siemens-
healthineers.com
Date: 2019.02.10 18:35:48 -05'00'

Signature:

卷之三

Date _____

Document No. Doc DM RCRP DF34 Ver. 3.0

Siemens
ECS Datasheets

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:

Catalogue Number (REF):

Siemens Material Number (SMN): 100115013

Classification:

Conformity Assessment Route:

Document Control Number: Doc_DM_Cuvette Cartridge_D828

Version: 4.0

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

Signature: 
Victor Canfield
DN 071-Carroll-Victor Canfield-Siemens,
email:mcarroll@siemens.com
Healthcareers.com
Date: 2013-02-21:10:13 -05:00

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

Date _____

Document No. DoC_DM_Cuvette Cartridge_D828 Ver. 4.0

SIEMENS

EC Declaration of Conformity

CE

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:

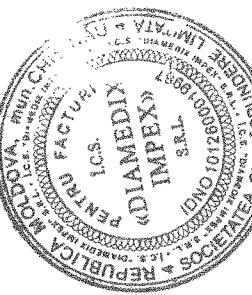
DoC_DM_DV_Sample Cups_DSC4

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.



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.	

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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

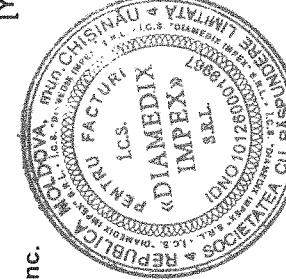
This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Inc.

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

Signature:

Carrio
Victor

2019-02-19

Date
[YYYY-MM-DD]

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

Document No.: DoC_DM_CHEM_I_CAL_DC18C Ver. 3.0