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:	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 — 2016/03/30

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

Date
[YYYY-MM-DD]

EC DECLARATION OF CONFORMITY

REPUBLICA MOLDOVA · SOCIETATEA CU RĂSPUNDERE LIMITATĂ · Î.C.S. «DIAMEDIX IMPEX» S.R.L.

SIEMENS

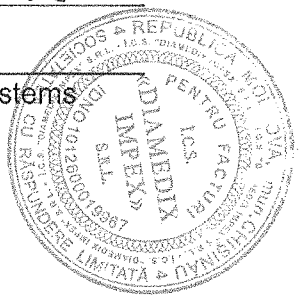
CE

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® Amylase Flex® reagent cartridge (AMY)
Cat. No. (REF)	DF17A
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

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

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

2016/06/02

Date
[YYYY-MM-DD]

EC DECLARATION OF CONFORMITY

SIEMENS

CE

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

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:	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 2017-0

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

Date
[YYYY-MM-DD]

EC DECLARATION OF CONFORMITY

SIEMENS

EC Declaration of Conformity

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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® 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

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

2016/08/12

Date
[YYYY-MM-DD]

EC DECLARATION OF CONFORMITY

SIEMENS

EC Declaration of Conformity

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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

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

2016/08/11

Date
[YYYY-MM-DD]

EC DECLARATION OF CONFORMITY

SIEMENS

CE

Declaration of Conformity

We hereby declare that the in vitro diagnostic devices and / or accessories described below conform to the Annex I Essential Requirements of Directive 98/79/EC.

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

Product:	Dimension® Total Protein Flex® reagent cartridge (TP)
Cat. No. (REF)	DF73
Manufacturer Address:	Siemens Healthcare Diagnostics Inc. 500 GBC Drive P.O. Box 6101 Newark, Delaware 19714-6101
EU Authorized Representative:	Siemens Healthcare Diagnostics Ltd. Sir William Siemens Sq. Frimley, Camberley, UK GU16 8QD
Date:	2008-07-01
Authorization:	Signature Julie L Feaster Print Julie L. Feaster Regulatory Affairs & Quality Systems Representative

SIEMENS

EC Declaration of Conformity

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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® 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:	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
[YYYY-MM-DD]

EC DECLARATION OF CONFORMITY

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:	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 Ltd. Sir William Siemens Square Frimley, Camberley, GU16 8QD, UK
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:	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

2016/12/12

Date
[YYYY-MM-DD]

EC DECLARATION OF CONFORMITY