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
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.
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 21:01:13 -05'00'

2019-02-10

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

Date [YYYY-MM-DD]

REPUBLICA MOLDOVA, mun. CHISINAU
PENTRU FACTURI
I.C.S. «DIAMEDIX IMPEX» S.R.L.
IDNO 1012600041996
SOCIETATEA CU RASPUNDERE LIMITATA

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® 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

REPUBLICA MOLDOVA PENTRU FACTURI L.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019907 SOCIETATEA CU RASPUNDERE LIMITATA

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® 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 Date [YYYY-MM-DD] 2015/10/27

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

REPUBLICA MOLDOVA PENTRU FACTURI L.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600018987 SOCIETATEA CU RASPUNDERE LIMITATA

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:	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

2016/06/02

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

Date [YYYY-MM-DD]

I.C.S. «DIAMEDIX IMPEX» S.R.L.

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:	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]

REPUBLICA MOLDOVA PENTRU FABRICANTII DE DISPOZITIVE MEDICALE L.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600015961 SOCIETATEA CU RASPUNDERE LIMITATA

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:	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

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

Date 2016/10/27
[YYYY-MM-DD]

I.C.S. «DIAMEDIX IMPEX» S.R.L.

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:	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

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

20/06/22

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

Date
[YYYY-MM-DD]

REPUBLICA ROMÂNIA CENTRUL DE ACTIVITĂȚI I.C.S. «DIAMEDIX IMPEX» S.R.L. SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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:	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 2016/08/12

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

Date
[YYYY-MM-DD]

REPUBLICA MOLDOVA PENTRU FACTURI I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012800019967 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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

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® 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

«DIAMEDIX IMPEX» S.R.L.

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® 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:	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 Ayash 07/06/05

Rebecca Ayash
Senior Director Regulatory Affairs
Siemens Healthcare Diagnostics
Newark, DE 19714

Date [YYYY-MM-DD]

«DIAMEDIX IMPEX» S.R.L.

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:	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

2017-09-11
Date
[YYYY-MM-DD]

REPUBLICA MOLDOVA mun. CHIȘINĂU PENTRU FACTURI I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600016681 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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:	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

REPUBLICA MOLDOVA PENTRU FACTURI I.C.S. «DIAMEDIX IMPEX» S.R.L.

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® 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

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

Date [YYYY-MM-DD] 2016/07/20

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:	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® Bilirubin Calibrator
Catalogue Number (REF):	DC167
Siemens Material Number (SMN):	10445013
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Control Number:	DoC_DM_TBI.DBI CAL_DC167
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 20:28:54 -05'00'

2019-02-10

Date [YYYY-MM-DD]

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

REPUBLICA MOLDOVA, mun. CHIŞINĂU, PENTRU FACTURI, I.C.S. «DIAMEDIX IMPEX» S.R.L., IDNO 1012600019367, SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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 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=victor.m.carrio@siemens-healthineers.com
Date: 2019.02.10 20:19:17 -05'00'

2019-02-10

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

Date [YYYY-MM-DD]