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.

Digitally signed by Marinescu Traian Alin
Date: 2021.02.26 10:00:01 EET
Reason: MoldSign Signature
Location: Moldova

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 — Digitally signed by Carrio Victor, DN: cn=Carrio Victor, o=Siemens, email=victor.m.carrio@siemens-healthineers.com, Date: 2019.02.10 21:55:10 -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 1012600019967, SOCIETATEA CU RASPUNDERE LIMITATA

UNCONTROLLED COPY

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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 FABRICANT I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019987 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 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

Digitally signed by Carrio Victor
DN: cn=Carrio Victor, o=Siemens, email=victor.m.carrio@siemens-healthineers.com
Date: 2019.02.10 19:42:48 -05'00'

2019-02-10

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

Date [YYYY-MM-DD]

REPUBLICA MOLDOVA, I.C.S. PENTRU FACTURI «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019647 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® 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.

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 19:47:38 -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. CHIȘINĂU, PENTRU FACTURI, I.C.S. «DIAMEDIX IMPEX» S.R.L., IDNO 1012600019647, SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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® 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]

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 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

Digitally signed by Ryan Sherrie
DN: serialNumber=Z0026ZFR, givenName=Sherrie, sn=Ryan, o=Siemens, cn=Ryan Sherrie
Date: 2019.02.12 23:54:05 -05'00'

Sherrie Ryan
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 1012600018967, SOCIETATEA CU RASPUNDERE LIMITATA

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 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, email=victor.m.carrio@siemens-healthineers.com
Date: 2019.02.10 18:00:38 -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 1012600018957
SOCIETATEA CU RASPUNDERE LIMITATA

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® 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

Digitally signed by Carrio Victor
DN: cn=Carrio Victor, o=Siemens, email=victor.m.carrio@siemens-healthineers.com
Date: 2019.02.10 21:14:09 -05'00'

2019-02-10

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

Date [YYYY-MM-DD]

REPUBLICA MOLDOVA, mun. CHIŞINĂU, PENTRU FACTURI, I.C.S. «DIAMEDIX IMPEX» S.R.L., IDNO 1012600019987, 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 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 2017-09-11

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

Date
[YYYY-MM-DD]

REPUBLICA MOLDOVA, mun. CHIŞINĂU, PENTRU FACTURI, I.C.S. «DIAMEDIX IMPEX» S.R.L., IDNO 1012600019967, 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 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® 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 1012600014987

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® 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

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]

REPUBLICA MOLDOVA PENTRU FACTURI I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019861 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® 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

Date 2016/08/11
(YYYY-MM-DD)

PENTRU FACTURI I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019967 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 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=victor.m.carrio@siemens-healthineers.com
Date: 2019.02.10 21:25:17 -05'00'

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

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

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® 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

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 18:20:46 -05'00'

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

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

REPUBLICA MOLDOVA, MUN. CHISINAU, PENTRU FACTURI, I.C.S. «DIAMEDIX IMPEX» S.R.L., IDNO 1012600019..., SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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, MUN. CHISINAU
PENTRU FACTURI
I.C.S.
«DIAMEDIX IMPEX»
S.R.L.
IDNO 1012600015967
SOCIETATEA CU RASPUNDERE LIMITATA

Siemens Healthcare Diagnostics Inc.

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

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® 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

2015/10/27

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

Date [YYYY-MM-DD]

REPUBLICA MOLDOVA mun. CHIȘINĂU 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® 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

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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® Calcium Flex® reagent cartridge
Catalogue Number (REF):	DF23A
Siemens Material Number (SMN):	10444949
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Control Number:	DoC_ DM_CA_DF23A
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 19:36:45 -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 1012800018961 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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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® 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

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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 [YYYY-MM-DD]

REPUBLICA MOLDOVA, mun. CHIŞINĂU, PENTRU FACTURI, I.C.S. «DIAMEDIX IMPEX» S.R.L., IDNO 1012600019987, 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® 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.

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Date: 2019.02.10 19:45:24 -05'00'

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

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REPUBLICA MOLDOVA, mun. CHIŞINĂU
PENTRU FACTURI
I.C.S. «DIAMEDIX IMPEX» S.R.L.
IDNO 1012600018987
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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 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

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

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Date: 2019.02.10 22:08:25 -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 1012600019961, SOCIETATEA CU RASPUNDERE LIMITATA

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 2016/06/22

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

Date [YYYY-MM-DD]

REPUBLICA MOLDOVA PENTRU FACTURA I.C.S. «DIAMEDIX IMPEX» S.R.L. ID NO 1012600019967 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 Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	Dimension® C-Reactive Protein Extended Range Flex® reagent cartridge
Catalogue Number (REF):	DF34
Siemens Material Number (SMN):	10444903
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Control Number:	DoC_ DM_RCRP_DF34
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

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Date: 2019.02.10 18:35:48 -05'00'

2019-02-10

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Newark, DE 19714

Date [YYYY-MM-DD]

REPUBLICA MOLDOVA, mun. CHIȘINĂU, PENTRU FACTURI, I.C.S. «DIAMEDIX IMPEX» S.R.L., IDNO 1012600019967, SOCIETATEA CU RĂSPUNDERE LIMITATĂ

SIEMENS

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

Signature: Carrio Victor

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Date: 2019.02.10 21:01:13 -05'00'

2019-02-10

Victor Carrio
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Siemens Healthcare Diagnostics, Inc.
Newark, DE 19714

Date [YYYY-MM-DD]

REPUBLICA MOLDOVA, mun. CHISINAU
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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.

REPUBLICA MOLDOVA, mun. CH... PENTRU FACTURI I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019... SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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® 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

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Date: 2019.02.19 17:10:25 -05'00'

2019-02-19

Victor Carrio
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Date [YYYY-MM-DD]

REPUBLICA MOLDOVA, mun. CHIŞINĂU, I.C.S. PENTRU FACTURI I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019867 SOCIETATEA CU RĂSPUNDERE LIMITATĂ