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.

Digitally signed by Marinescu Traian Alin
Date: 2019.02.25 11:29:16 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 21:56:10 -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. CHIŞINĂU, I.C.S. "DIAMEDIX IMPEX" S.R.L., PENTRU FACTURI, I.C.S. "DIAMEDIX IMPEX" S.R.L., IDNO 1012600019867, SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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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® 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]

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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® 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:	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 19:41:40 -05'00'

2019-02-10

Victor Carrio
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Date [YYYY-MM-DD]

REPUBLICA MOLDOVA, mun. CHISINAU
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I.C.S. «DIAMEDIX IMPEX» S.R.L.
IDNO 1012600018967
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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® 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:	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 19:53:48 -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. CHIŞINĂU
PENTRU FACTURI
Î.C.S. «DIAMEDIX IMPEX» S.R.L.
IDNO 1012600018967
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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® Urea Nitrogen Flex® reagent cartridge
Catalogue Number (REF):	DF21
Siemens Material Number (SMN):	10444969
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Control Number:	DoC_ DM_BUN_DF21
Version:	3.0

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

Signature: Carrio Victor

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Date: 2019.02.10 19:50:06 -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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IDNO 1012600019967
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Place of Manufacture:	Siemens Healthcare Diagnostics Inc. 500 GBC Drive, Mailstop 514, P.O. Box 6101 Newark, DE, 19714, USA
EC Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	Dimension® Creatinine Flex® reagent cartridge
Catalogue Number (REF):	DF33B
Siemens Material Number (SMN):	10872079
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Control Number:	DoC_ DM_CRE2_DF33B
Version:	3.0

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

Signature: Carrio Victor

Digitally signed by Carrio Victor
DN: cn=Carrio Victor, o=Siemens, email=victor.m.carrio@siemens-healthineers.com
Date: 2019.02.10 22:09:31 -05'00'

2019-02-10

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

Date [YYYY-MM-DD]

REPUBLICA MOLDOVA, mun. CHISINAU
PENTRU FACTURI
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IDNO 1012600019967
SOCIETATEA CU RASPUNDERE LIMITATA

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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® 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:	3.0

This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Inc.
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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 19:51:15 -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 RĂSPUNDERE LIMITATĂ

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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® Total Protein Flex® reagent cartridge
Catalogue Number (REF):	DF73
Siemens Material Number (SMN):	10444979
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Control Number:	DoC_ DM_TP_DF73
Version:	3.0

This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Inc.
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Signature: Carrio Victor

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Date: 2019.02.10 19:57:29 -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
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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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DN: cn=Carrio Victor, o=Siemens, email=victor.m.carrio@siemens-healthineers.com
Date: 2019.02.19 17:10:25 -05'00'

2019-02-19

Victor Carrio
Sr. Manager Regulatory Affairs
Siemens Healthcare Diagnostics, Inc.
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Date
[YYYY-MM-DD]

REPUBLICA MOLDOVA, mun. CHISINAU
PENTRU FACTURI
Î.C.S. «DIAMEDIX IMPEX» S.R.L.
IDNO 1012600019967
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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:	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 Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
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:	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 20:17:57 -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, I.C.S. DIAMEDIX IMPEX S.R.L., PENTRU FACTURI, I.C.S. «DIAMEDIX IMPEX» S.R.L., IDNO 1012600019967, SOCIETATEA CU RASPUNDERE LIMITATA

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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:	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.CHI... PENTRU FACTURI I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600018967 SOCIETATEA CU RASPUNDERE...

SIEMENS

EC Declaration of Conformity

Signature: Ryan Sherrie

Digitally signed by Ryan Sherrie
DN: serialNumber=Z0026ZFR, givenName=Sherrie, sn=Ryan, o=Siemens, cn=Ryan Sherrie
Reason: I am approving this document
Date: 2020.11.09 10:03:23 -05'00'

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

Date
[YYYY-MM-DD]

REPUBLICA MOLDOVA, mun. C... I.C.S. "DIAMEDI... IMPEX..." S.R.L. PENTRU FACTU... IDNO 1012600... SOCIETATEA CU RĂSP...

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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 — 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]