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.<br>500 GBC Drive, Mailstop 514, P.O. Box 6101<br>Newark, DE, 19714, USA |
| **Place of Manufacture:** | Nypro Mebane<br>1018 Corporate Park Drive<br>Mebane, North Carolina, 27302, USA<br><br>Currier Plastics, Inc.<br>101 Columbus Street<br>Auburn, New York, 13021, USA |
| **EC Authorized Representative:** | Siemens Healthcare Diagnostics Manufacturing Ltd.<br>Chapel Lane<br>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. CHIȘINĂU
PENTRU FACTURI
I.C.S. «DIAMEDIX IMPEX» S.R.L.
IDNO 1012600016987
SOCIETATEA CU RĂSPUNDERE LIMITATĂ



Digitally signed by Marincescu Traian alin
Date: 2022.11.10 17:34:11 EET
Reason: MoldSign Signature
Location: Moldova

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.<br>500 GBC Drive, Mailstop 514, P.O. Box 6101<br>Newark, DE, 19714, USA |
| EC Authorized Representative: | Siemens Healthcare Diagnostics Ltd.<br>Sir William Siemens Square<br>Frimley, Camberley, GU16 8QD, UK |
| 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: | 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

2016/08/05

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 1012600018996 SOCIETATEA CU RASPUNDERE LIMITATA

EC DECLARATION OF CONFORMITY

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.<br>500 GBC Drive<br>P.O. Box 6101<br>Newark, Delaware 19714-6101 |
| **EU Authorized Representative:** | Siemens Healthcare Diagnostics Ltd.<br>Sir William Siemens Sq.<br>Frimley, Camberley, UK GU16 8QD |
| **Date:** | 2008-07-01 |
| **Authorization:** | Signature Julie L Feaster<br>Print Julie L. Feaster<br>Regulatory Affairs & Quality Systems Representative |

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

**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.<br>500 GBC Drive, Mailstop 514, P.O. Box 6101<br>Newark, DE, 19714, USA |
| **Place of Manufacture:** | Siemens Healthcare Diagnostics Inc.<br>500 GBC Drive, Mailstop 514, P.O. Box 6101<br>Newark, DE, 19714, USA |
| **EC Authorized Representative:** | Siemens Healthcare Diagnostics Ltd.<br>Sir William Siemens Square<br>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 mun. CHISINAU 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.<br>500 GBC Drive, Mailstop 514, P.O. Box 6101<br>Newark, DE, 19714, USA |
| **Place of Manufacture:** | Siemens Healthcare Diagnostics Inc.<br>500 GBC Drive, Mailstop 514, P.O. Box 6101<br>Newark, DE, 19714, USA |
| **EC Authorized Representative:** | Siemens Healthcare Diagnostics Ltd.<br>Sir William Siemens Square<br>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]**

REPUBLICA MOLDOVA PENTRU PRODUCATORI 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.<br>500 GBC Drive, Mailstop 514, P.O. Box 6101<br>Newark, DE, 19714, USA |
| **Place of Manufacture:** | Siemens Healthcare Diagnostics Inc.<br>500 GBC Drive, Mailstop 514, P.O. Box 6101<br>Newark, DE, 19714, USA |
| **EC Authorized Representative:** | Siemens Healthcare Diagnostics Ltd.<br>Sir William Siemens Square<br>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 I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 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.<br>500 GBC Drive, Mailstop 514, P.O. Box 6101<br>Newark, DE, 19714, USA |
| **Place of Manufacture:** | Siemens Healthcare Diagnostics Inc.<br>500 GBC Drive, Mailstop 514, P.O. Box 6101<br>Newark, DE, 19714, USA |
| **EC Authorized Representative:** | Siemens Healthcare Diagnostics Ltd.<br>Sir William Siemens Square<br>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 MUN. CHIȘINĂU SOCIETATEA CU RĂSPUNDERE LIMITATĂ
PENTRU FACTURI
I.C.S. «DIAMEDIX IMPEX» S.R.L.
IDNO 1012600019967

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.<br>500 GBC Drive, Mailstop 514, P.O. Box 6101<br>Newark, DE, 19714, USA |
| **Place of Manufacture:** | Siemens Healthcare Diagnostics Inc.<br>500 GBC Drive, Mailstop 514, P.O. Box 6101<br>Newark, DE, 19714, USA |
| **EC Authorized Representative:** | Siemens Healthcare Diagnostics Manufacturing Ltd.<br>Chapel Lane<br>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. CHIŞINĂU
PENTRU FACTURI
I.C.S. «DIAMEDIX IMPEX» S.R.L.
IDNO 1012600019967
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.<br>500 GBC Drive, Mailstop 514, P.O. Box 6101<br>Newark, DE, 19714, USA |
| **Place of Manufacture:** | Siemens Healthcare Diagnostics Inc.<br>500 GBC Drive, Mailstop 514, P.O. Box 6101<br>Newark, DE, 19714, USA |
| **EC Authorized Representative:** | Siemens Healthcare Diagnostics Manufacturing Ltd.<br>Chapel Lane<br>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

Digitally signed by Carrio Victor
DN: cn=Carrio Victor, o=Siemens, email=victor.m.carrio@siemens-healthineers.com
Date: 2019.02.10 19:50:06 -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

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.<br>500 GBC Drive<br>P.O. Box 6101<br>Newark, Delaware 19714-6101 |
| **EU Authorized Representative:** | Siemens Healthcare Diagnostics Ltd.<br>Sir William Siemens Sq.<br>Frimley, Camberley, UK GU16 8QD |
| **Date:** | 2008-07-01 |
| **Authorization:** | Signature Julie L Feaster<br>Print Julie L. Feaster<br>Regulatory Affairs & Quality Systems Representative |

I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019687

**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.<br>500 GBC Drive, Mailstop 514, P.O. Box 6101<br>Newark, DE, 19714, USA |
| **Place of Manufacture:** | Siemens Healthcare Diagnostics Inc.<br>500 GBC Drive, Mailstop 514, P.O. Box 6101<br>Newark, DE, 19714, USA |
| **EC Authorized Representative:** | Siemens Healthcare Diagnostics Manufacturing Ltd.<br>Chapel Lane<br>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

Digitally signed by Carrio Victor
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. CHISINAU
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.<br>500 GBC Drive, Mailstop 514, P.O. Box 6101<br>Newark, DE, 19714, USA |
| Place of Manufacture: | Siemens Healthcare Diagnostics Inc.<br>500 GBC Drive, Mailstop 514, P.O. Box 6101<br>Newark, DE, 19714, USA |
| EC Authorized Representative: | Siemens Healthcare Diagnostics Ltd.<br>Sir William Siemens Square<br>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 (YYYY-MM-DD): 2016/08/11

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

EC DECLARATION OF CONFORMITY

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.<br>500 GBC Drive<br>P.O. Box 6101<br>Newark, Delaware 19714-6101 |
| **EU Authorized Representative:** | Siemens Healthcare Diagnostics Ltd.<br>Sir William Siemens Sq.<br>Frimley, Camberley, UK GU16 8QD |
| **Date:** | 2008-07-01 |
| **Authorization:** | Signature Julie L Feaster<br>Print Julie L. Feaster<br>Regulatory Affairs & Quality Systems Representative |