

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.

Siemens Healthcare Diagnostics Inc.
500 GBC Drive, Mailstop 514, P.O. Box 6101
Newark, DE, 19714, USA

Siemens Healthcare Diagnostics Inc.
500 GBC Drive, Mailstop 514, P.O. Box 6101
Newark, DE, 19714, USA

Siemens Healthcare Diagnostics Manufacturing Ltd.
Chapel Lane
Swords, Co. Dublin, Ireland

Dimension® Alkaline Phosphatase Flex® reagent cartridge

DF150

10642445

General IVD

ANNEX III

DoC DM ALPI DF150

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.

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 -0500

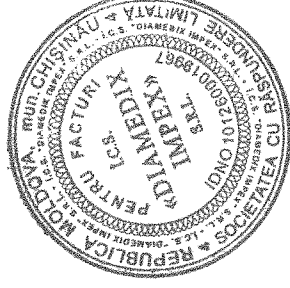
Victor

2019-02-10

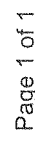
Victor Carrio
Sr. Manager Regulatory Affairs

Siemens Healthcare Diagnostics Inc.
Newark, DE 19714

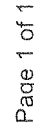
[YYY-MM-DD]



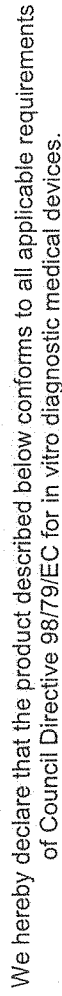
EC Declaration of Conformity



EC Declaration of Conformity



EC Declaration of Conformity



Page 1 of 1

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.

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

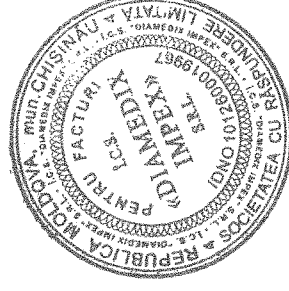
Digitally signed by Carrio Victor
DN: cn=Carrio Victor, o=Siemens,
email=carrio.victor@siemens-
healthcare.com
Date: 2019.02.10 19:50:06 +05'00'

2019-02-10

Victor Carrio

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

Date
[YYYY-MM-DD]



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.

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® 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.*

Carrio
Victor

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

Signature:

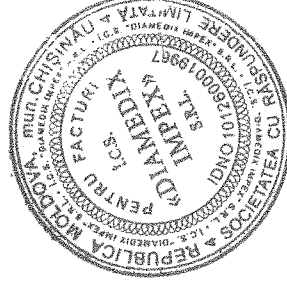
2019-02-10

Victor Carrio

Date

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

[YYYY-MM-DD]



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.

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.
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=carrio.victor@siemens-healthcare.com,
date: 2019.02.10 19:51:15 +0500

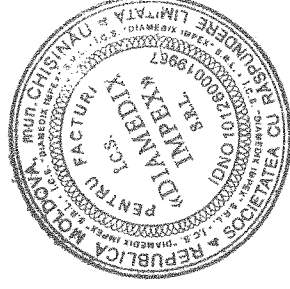
2019-02-10

Victor Carrio

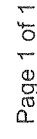
Sr. Manager Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
Newark, DE 19714

Date

[YYYY-MM-DD]



EC Declaration of Conformity



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.

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

Digitally signed by Carrio Victor
DN: cn=Carrio Victor, o=Siemens,
email=victor.m.carrio@siemens-
healthineers.com
Date: 2019.02.19 17:10:25 -05'00'

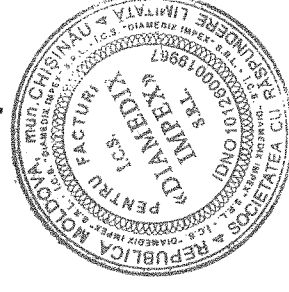
2019-02-19

Victor Carrio

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

Date

[YYYY-MM-DD]



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.

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=carrio.victor@siemens-healthineers.com
Date: 2019.02.10 20:17:57 -05'00'

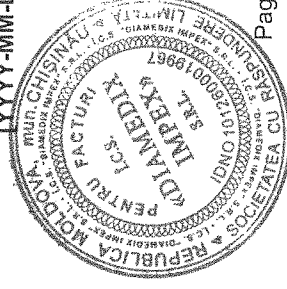
2019-02-10

Victor Carrio

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

Date

YYYY-MM-DDJ



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.

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

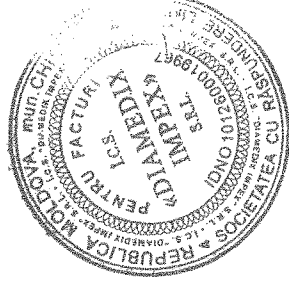
Document Control Number:

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.*



EC Declaration of Conformity

Ryan Sherrie

Signature:

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'

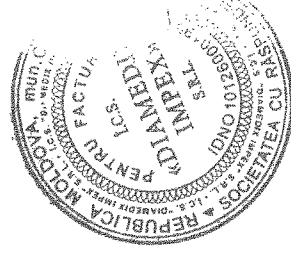
Sherrie Ryan

Director Regulatory Affairs

Siemens Healthcare Diagnostics, Inc.
Newark, DE 19714

Date

[YYYY-MM-DD]



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.

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=carrio.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]

