

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.

Legal Manufacturer: Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY, 10591-5097, USA

Place of Manufacture: ThermoFisher Scientific
8365 Valley Pike
Middletown, VA, 22645-0307, USA

EC Authorized Representative: Siemens Healthcare Diagnostics Ltd.
Sir William Siemens Square
Frimley, Camberley, GU16 8QD, UK

Product Name: ADVIA 120/2120/2120i Sheath/Rinse

Catalogue Number (REF): 02337140 (10L)
01554628 (20L)

Siemens Material Number (SMN): 10316869 (10L)
10312272 (20L)

Legacy Product Code: T01-3664-01 (10L)
T01-3623-01 (20L)

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Control Number: DoC_ADVIA 120/2120/2120i Sheath/Rinse

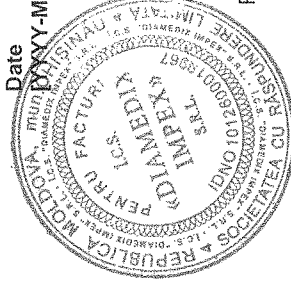
Version: 1.0

*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:  Digitally signed by Gee Matthew
Date: 2015.11.12 16:04:01 -05'00'

2015-11-12

Date 2015-11-12
Signature MXY-MM-DDJ



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Place of Manufacture:

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Middletown, VA, 22645-0307, USA

EC Authorized Representative:

Siemens Healthcare Diagnostics Ltd.
Sir William Siemens Square
Frimley, Camberley, GU16 8QD, UK

Product Name:

ADVIA 120/2120/2120i PEROX SHEATH

Catalogue Number (REF):

03624240

Siemens Material Number (SMN):

10312275

Legacy Product Code:

T01-3633-54

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Control Number:

DoC_ADVIA 120/2120/2120i PEROX SHEATH

Version:

1.0

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Signature:

Digitally signed by Gee Matthew
Date: 2015.11.12 16:02:33 -05'00'

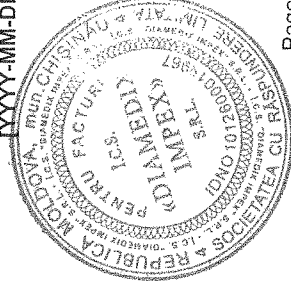
2015-11-12

Matthew Gee

**Sr. Manager, Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
Tarrytown, NY, USA**

Date

2015-11-12



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Place of Manufacture: ThermoFisher Scientific
8365 Valley Pike
Middletown, VA, 22645-0307, USA

EC Authorized Representative: Siemens Healthcare Diagnostics Ltd.
Sir William Siemens Square
Frimley, Camberley, GU16 8QD, UK

Product Name: ADVIA 120/2120/2120i EZ WASH

Catalogue Number (REF): 04871500

Siemens Material Number (SMN): 10285021

Legacy Product Code: N/A

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Control Number: DoC_ADVIA 120/2120/2120i EZ WASH

Version: 1.0

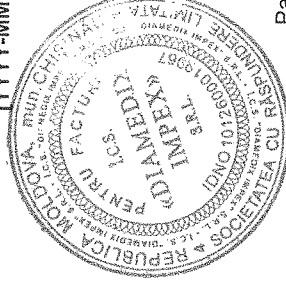
*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Inc.
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Signature:  Digitally signed by Gee Matthew
Date: 2015.11.12 16:00:43 -05'00'

2015-11-12

Date [YYYY-MM-DD]
[YYYY-MM-DD]

Matthew Gee
Sr. Manager, Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
Tarrytown, NY, USA



EC DECLARATION OF CONFORMITY

EU 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.
511 Benedict Avenue
Tarrytown, NY, 10591, USA

Place of Manufacture:

Streck
7002 South 109th Street
La Vista, NE, 68128, USA

EU Authorized Representative:

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

Product Name:

ADVIA 120/2120/2120i TESTpoint Hematology Controls

Catalogue Number (REF):

00848547 (Low Control)
05147873 (Norm Control)
08822644 (High Control)

Siemens Material Number (SMN):

10312287 (Low Control)
10312289 (Norm Control)
10312291 (High Control)

Legacy Product Code:

T03-3686-54 (Low Control)
T03-3687-54 (Norm Control)
T03-3688-54 (High Control)

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Identifier:

DoC_ADVIA 120/2120/2120i TESTpoint Controls

Version:

2.1

*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Inc.
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511 Benedict Avenue
Tarrytown, NY, 10591-5097, USA

Place of Manufacture: Streck
7002 South 109th Street
La Vista, NE, 68128, USA

EC Authorized Representative: Siemens Healthcare Diagnostics Ltd.
Sir William Siemens Square
Frimley, Camberley, GU16 8QD, UK

Product Name: ADVIA 120/2120/2120i SETpoint Calibrator

Catalogue Number (REF): 09170071

Siemens Material Number (SMN): 10312285

Legacy Product Code: T03-3685-52

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Control Number: DoC_ADVIA 120/2120/2120i SETpoint Cal

Version: 1.0

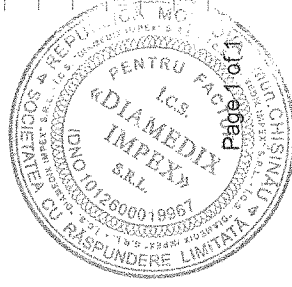
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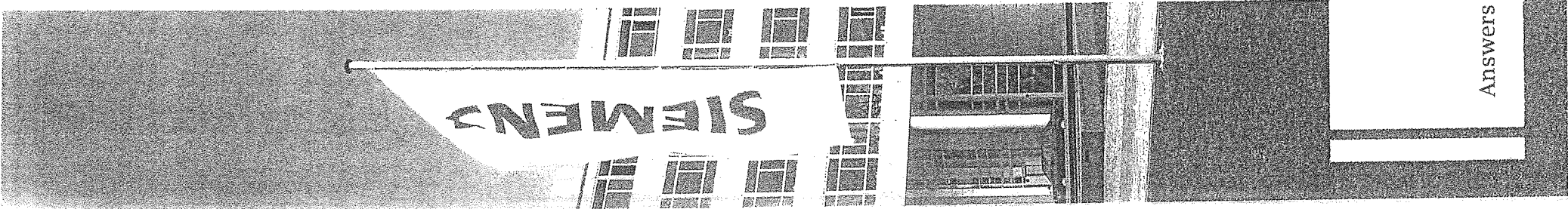
Signature:  Digitally signed by Gee Matthew
Date: 2015.11.12 16:03:16 -05'00'

2015-11-12

Date
[YYYY-MM-DD]

Matthew Gee
Sr. Manager, Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
Tarrytown, NY, USA





Daniel Tudor

Siemens Healthcare Diagnostics confirm
that the participant
has passed successfully the training

**ADVIA 2120/120 Field Service Training
(EMEA)**

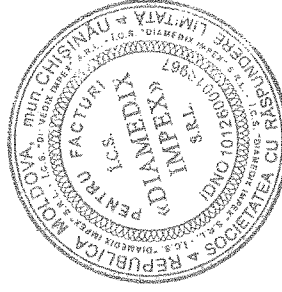
from

10.09.2012 to 28.09.2012

Eschborn, 28.09.2012

A handwritten signature in black ink, appearing to read 'P. Renard', written over a horizontal line.

Philippe Renard
Trainer



SIEMENS

Answers for life.

Certificat de instruire interna

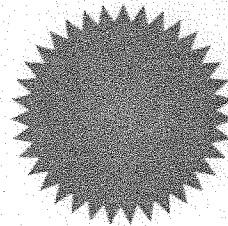
se acorda

D-lui Dumitru Curcubet

pentru participarea la instruirea pe analizorul

Advia 2120 i

perioada: 26-30.06.2017



Lector

Daniel Feldman

Digitally signed by Cipriela Alexandru
DN: cn=Cipriela Alexandru, o=Medix
Apex S.R.L., ou=Medix Apex S.R.L.,
c=Romania

