

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 CN-Free CBC TIMEPAC

Catalogue Number (REF):

08008297

Siemens Material Number (SMN):

10341169

Legacy Product Code:

T01-3626-52

Classification:

General IVD

Conformity Assessment Route:

ANNEX III

Document Control Number:

DoC_ADVIA 120/2120/2120i CN-Free CBC TIMEPAC

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:

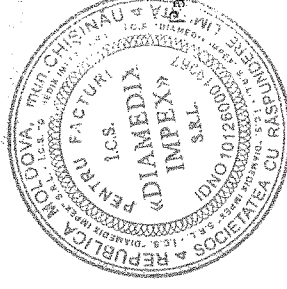
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Date: 2015.11.12 15:55:30 -05'00'

2015-11-12

Matthew Gee

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

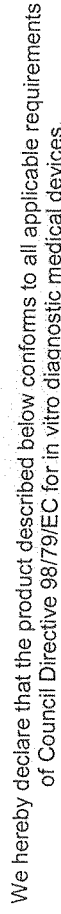
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Document No. DoC_ADVIA 120/2120/2120i CN-Free CBC TIMEPAC Ver. 1.0

Page 1 of 1

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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

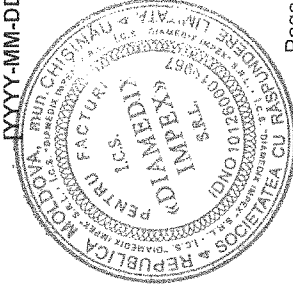
Matthew Gee

Sr. Manager, Regulatory Affairs

Siemens Healthcare Diagnostics Inc.
Tarrytown, NY, USA

21

XXXX-MM-DD



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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

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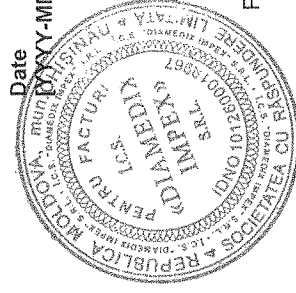
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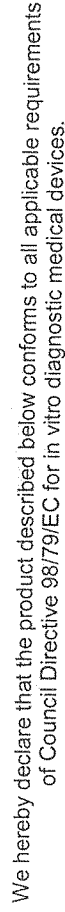
Matthew Gee

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



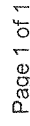
Date
2015-11-12

EC Declaration of Conformity



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[YYYY-MM-DD]



EU Declaration of Conformity



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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

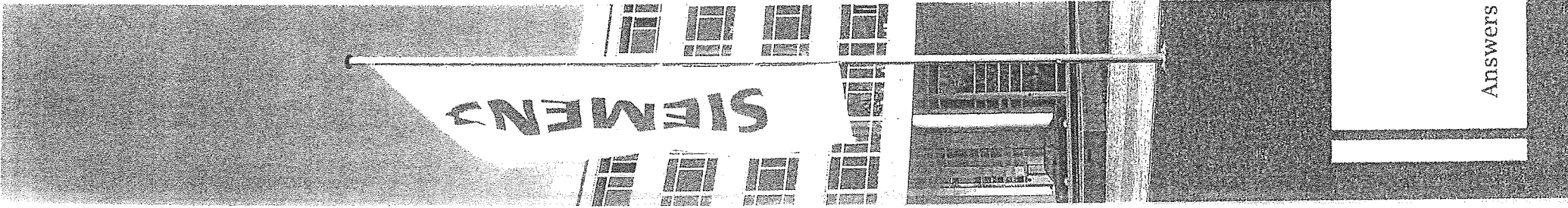
Document Identifier:

DoC_ADVIA 120/2120/2120i TESTpoint Controls

Version:

2.1

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Daniel Tudor

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

ADVIA 2120/120 Field Service Training (EMEA)

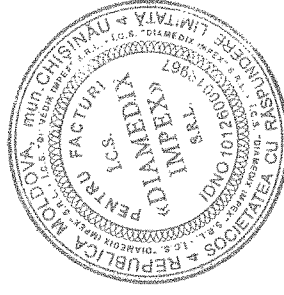
from

10.09.2012 to 28.09.2012

Eschborn, 28.09.2012

A handwritten signature in black ink, appearing to read 'Philippe Renard'.

Philippe Renard
Trainer



SIEMENS

Answers for life.