

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:

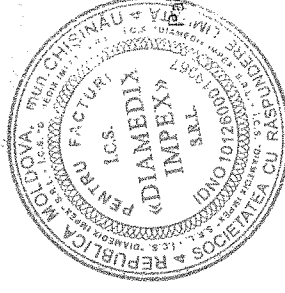
Matthew Gee
Digitally signed by Gee, Matthew
Date: 2015.11.12 15:55:30 -05'00'

2015-11-12

Matthew Gee

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

Date
[YYYY-MM-DD]



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

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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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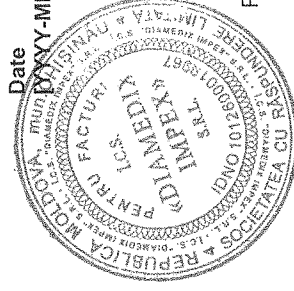
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Date: 2015.11.12 16:04:01 -05'00'

2015-11-12

Matthew Gee

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



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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 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:

Matthew Gee

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

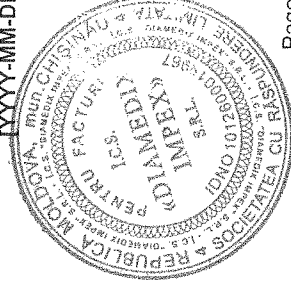
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Matthew Gee

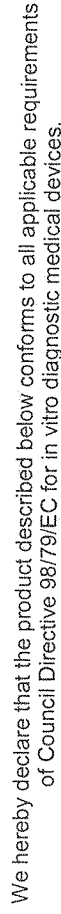
Sr. Manager, Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
Tarrytown, NY, USA

Date

XXXX-MM-DD]



EC Declaration of Conformity



Page 1 of 1

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:

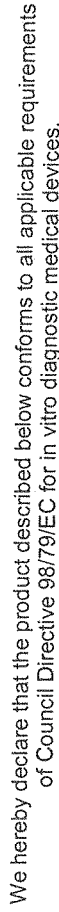
DoC_ADVIA 120/2120/2120i TESTpoint Controls

Version:

2.1

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EC Declaration of Conformity



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

ThermoFisher Scientific
8365 Valley Pike
Middletown, VA, 22645-0307, USA

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

ADVIA 120/2120/2120i OPTpoint

08100525

10312283

T03-3682-54

General IVD

ANNEX

DoC_ADVIA 120/2120/2120i OPTIpoint

10.

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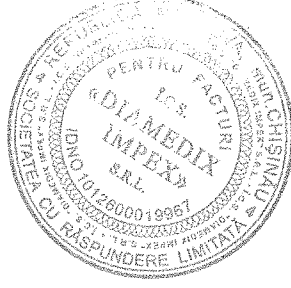
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Matthew Gee

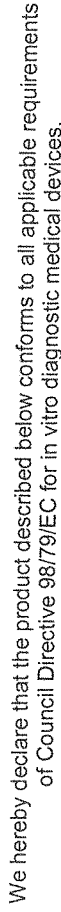
Sr. Manager, Regulatory Affairs

Siemens Healthcare Diagnostics Inc.
Tarrytown, NY, USA

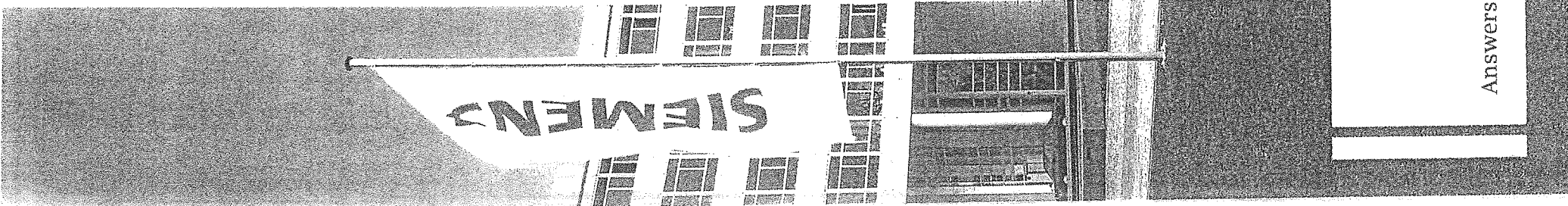
Date [YYYY-MM-DD]



EC Declaration of Conformity



Document No. DoC ADVIA 120/2120/2120i SETpoint Cal Ver. 1.0



Answers for life.

Daniel Tudor

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

ADVIA 2120/120 Field Service Training (EMEA)

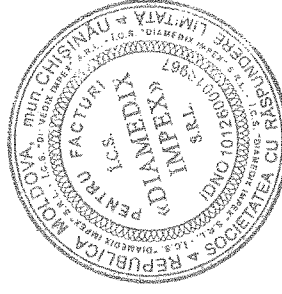
from

10.09.2012 to 28.09.2012

Eschborn, 28.09.2012

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

Philippe Renard
Trainer



SIEMENS

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 Chirila Alexandru
DN: cn=Chirila Alexandru, o=Mediastart, ou=Mediastart, email=chirila.alexandru@mediastart.md
Reason: Mediastart Signature
Location: Moldova

