

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 CBC TIMEPAC

Catalogue Number (REF): 09826813

Siemens Material Number (SMN): 10312269

Legacy Product Code: T01-3620-52

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Control Number: DoC_ADVIA 120/2120/2120i CBC TIMEPAC

Version: 1.0

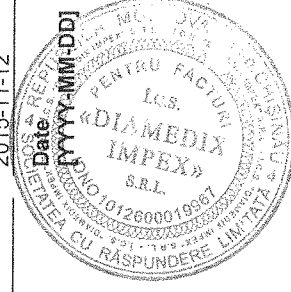
*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Inc.
This declaration supersedes any declaration issued previously for the same product.*

Signature:

Digitally signed by Gee Matthew
Date: 2015.11.12 15:54:48 -05'00'

2015-11-12

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



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Sir William Siemens Square
Frimley, Camberley, GU16 8QD, UK

Product Name: ADVIA 120/2120/2120i DIFF TIMEPAC

Catalogue Number (REF): 00739500

Siemens Material Number (SMN): 10312270

Legacy Product Code: T01-3621-52


Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Control Number: DoC_ADVIA 120/2120/2120i DIFF TIMEPAC

Version: 1.0

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Signature:  Digitally signed by Gee Matthew
Date: 2015.11.12 15:59:38 -05'00' 2015-11-12

Date [YYYY-MM-DD]
Matthew Gee
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Siemens Healthcare Diagnostics Inc.
Tarrytown, NY, USA



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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 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

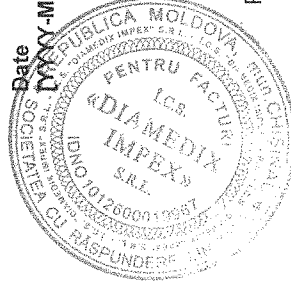
Version: 1.0

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Signature:  Digitally signed by Gee Matthew
Date: 2015.11.12 16:04:01 -0500

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 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'

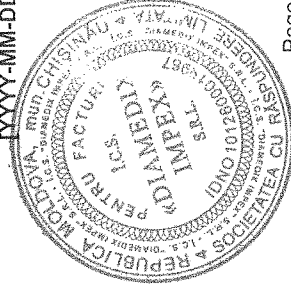
2015-11-12

Matthew Gee

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

Date

2015-11-12



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Legal Manufacturer:

Siemens Healthcare Diagnostics Inc.
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:

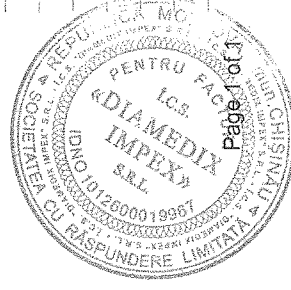
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Date: 2015.11.12 16:03:16 -05'00'

2015-11-12

Matthew Gee

Sr. Manager, Regulatory Affairs
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Date
[YYYY-MM-DD]



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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 OPTipoint

Catalogue Number (REF): 08100525

Siemens Material Number (SMN): 10312283

Legacy Product Code: T03-3682-54

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Control Number: DoC_ADVIA 120/2120/2120i OPTipoint

Version: 1.0

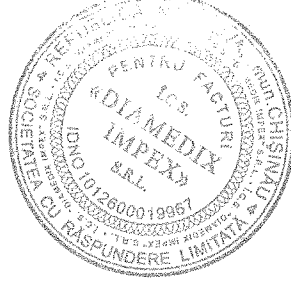
*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Inc.
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Signature:  Digitally signed by Gee Matthew
Date: 2015.11.12 16:01:44 -05'00'

2015-11-12

Date
[YYYY-MM-DD]

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



EC DECLARATION OF CONFORMITY

Certificat de instruire interna

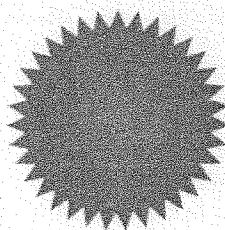
se acorda

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=Medix
Impex S.R.L., ou=Medix Impex S.R.L.,
c=Republica Moldova

