

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

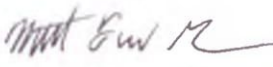
Classification: General IVD

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

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

Date
[YYYY-MM-DD]

2015-11-12

EC DECLARATION OF CONFORMITY

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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: 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

*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 16:03:16 -05'00'

2015-11-12

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

Date
[YYYY-MM-DD]

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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 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'

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

2015-11-12

Date
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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

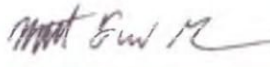
Classification: General IVD

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

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

2015-11-12
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[YYYY-MM-DD]

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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 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

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Signature:

Digitally signed by Gee Matthew
Date: 2015.11.12 16:01:44 -05'00'

2015-11-12

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

Date
[YYYY-MM-DD]

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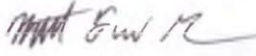
Legal Manufacturer:	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, NY, 10591-5097, USA
Place of Manufacture:	Streck 7002 South 109th Street La Vista NE, 68128, USA
EC Authorized Representative:	Siemens Healthcare Diagnostics Ltd. Sir William Siemens Square Frimley, Camberley, GU16 8QD, UK
Product Name:	ADVIA 120/2120/2120i 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 Control Number:	DoC_ADVIA 120/2120/2120i TESTpoint Controls
Version:	1.0

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SIEMENS

EC Declaration of Conformity

Signature:



Digitally signed by Gee Matthew
Date: 2015.11.12 16:04:42 -05'00'

2015-11-12

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

Date
[YYYY-MM-DD]

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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 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 -05'00'

2015-11-12

Matthew Gee
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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

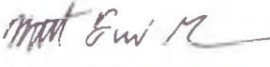
Classification: General IVD

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'

Matthew Gee
Sr. Manager, Regulatory Affairs
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 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

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

Date
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