SIEMENS

EC Declaration of Conformity

CE

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'

2015-11-12

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

Date
[YYYY-MM-DD]

EC DECLARATION OF CONFORMITY

SIEMENS

EC Declaration of Conformity

CE

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.
This declaration supersedes any declaration issued previously for the same product.

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]

EC DECLARATION OF CONFORMITY

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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.
This declaration supersedes any declaration issued previously for the same product.

Signature: Digitally signed by Gee Matthew
Date: 2015.11.12 16:00:43 -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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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

Date [YYYY-MM-DD]

EC DECLARATION OF CONFORMITY

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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

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 16:01:44 -05'00'

2015-11-12

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

Date [YYYY-MM-DD]

EC DECLARATION OF CONFORMITY

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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

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.

EC DECLARATION OF CONFORMITY

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]

EC DECLARATION OF CONFORMITY

SIEMENS

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:	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

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

Date
[YYYY-MM-DD]

EC DECLARATION OF CONFORMITY

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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 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

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 16:02:33 -05'00'

2015-11-12

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

Date
[YYYY-MM-DD]

EC DECLARATION OF CONFORMITY

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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 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

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 15:59:38 -05'00'

2015-11-12

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

Date [YYYY-MM-DD]

EC DECLARATION OF CONFORMITY