

# 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:** 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)

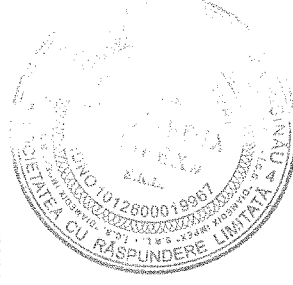
**Classification:** General IVD

**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.*



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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 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

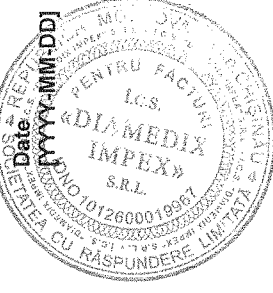
**Version:** 1.0

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**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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**Place of Manufacture:**

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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 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'

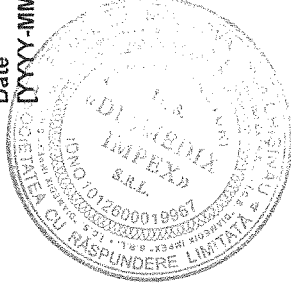
2015-11-12

Matthew Gee

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

Date  
[YYYY-MM-DD]

[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 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

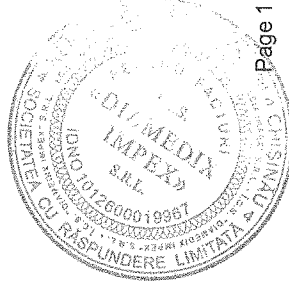
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**Signature:**  Digitally signed by Gee Matthew  
Date: 2015.11.12 16:00:43 -05'00'

2015-11-12

**Date**  
[YYYY-MM-DD]

Matthew Gee  
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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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**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



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