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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 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

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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