

## 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 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:**

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

2015-11-12

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

EC DECLARATION OF CONFORMITY