

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:

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

2015-11-12

Date
[YYYY-MM-DD]