



## Declaration of Conformity

**LEGAL MANUFACTURER:** Siemens Healthcare Diagnostics Inc.  
Tarrytown, New York 10591-5097  
U.S.A.

**PLACE OF MANUFACTURE:** JEOL Co. Ltd.  
1-2 Musashino 3-CHOME  
Akishima  
Tokyo 196-8558 Japan

**PRODUCT CATEGORY:** Consumable

**PRODUCT:** ADVIA Chemistry Systems Consumables (Attachment 1)

**CLASSIFICATION:** Self Declaration

**CONFORMITY ASSESSMENT ROUTE:** Annex III applied

**STANDARDS APPLIED:** EN 980:2003 Graphical Symbols for Use in the Labeling of Medical Devices

**DOCUMENT SYSTEM MANAGEMENT No:** 18-33-02

**REV:** 3.0

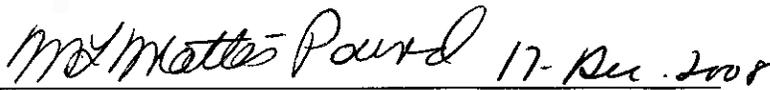
We herewith declare that the above-mentioned product(s) meet the provisions of the Council Directive 98/79/EC for in vitro diagnostic medical devices. The Manufacturer retains all supporting documentation.

Attachment 1		
REF (BAN) Number:	Product Code	Description
01390706	073-0157-02	ADVIA Chemistry Systems Sample Cup
08313370	073-0152-02	ADVIA 1650/2400 Brown Reagent Wedge
08771802	073-0078-02	ADVIA 1650 Peristaltic Pump Tube

*Siemens Healthcare Diagnostics Inc. is the current legal manufacturer of all diagnostics products previously manufactured by Siemens Medical Solutions Diagnostics. During a transition period to update product labeling and customer documentation to indicate Siemens Healthcare Diagnostics Inc. as the legal manufacturer, products may be identified and labeled as either Siemens Healthcare Diagnostics Inc. or Siemens Medical Solutions Diagnostics.*

*This Declaration of Conformity is applicable for either Siemens Healthcare Diagnostics Inc., or Siemens Medical Solutions Diagnostics labeled products.*

Siemens Healthcare Diagnostics Inc.  
Tarrytown, New York, USA

  
Mary Lou Mattes-Pound      Date  
Director of Quality Systems and Compliance