



## EC Declaration of Conformity

Manufacturer: QUIDEL Corporation  
10165 McKellar Court  
San Diego, California 92121  
USA

Product Names: RapidVue® hCG test (Catalog #00257)

Description: The RapidVue hCG test is intended for the rapid, qualitative detection of human chorionic gonadotropin (hCG) in urine for the early detection of pregnancy.

Classification: General In Vitro Diagnostic Device

Conformity Assessment Route: Annex III of Council Directive 98/79/EC Concerning In vitro diagnostic devices

Estimated Start of CE-Marking: May 4, 2004

QUIDEL Corporation, being the manufacturer/distributor within the European Economic Area hereby declares that the products covered by the declaration conform with the Essential Requirements of EC Directive 98/79/EC. All supporting documentation is retained under the premises of the manufacturer.

This declaration is valid for all devices described in this document.

Signed: \_\_\_\_\_

Jennifer S. Hankard  
Regulatory Affairs Manager  
QUIDEL Corporation  
10165 McKellar Court  
San Diego, California 92121  
USA

Date: \_\_\_\_\_

May 4, 2004