



## EC Declaration of Conformity

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

Product Names: QuickVue® Chlamydia Test (Catalog #0B006, #0B008, and #0B009)

Description: The QuickVue Chlamydia test is intended for the rapid, qualitative detection of chlamydia. The test is intended for use as an aid in the presumptive diagnosis of chlamydial infection.

Classification: List B In Vitro Diagnostic Device

Conformity Assessment Route: Annex IV section 3 of Directive 98/79/EC of the European Parliament and the Council on in-vitro diagnostic medical devices.

Estimated Start of CE-Marking: December 2, 2003

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 and have been subject to the Conformity Assessment procedures defined in Article 9 under the supervision of TUV Product Service GmbH, a Notified Body carrying the number 0123. All supporting documentation is retained under the premises of the manufacturer.

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

The declaration is supported by an EC Certificate issued by TUV Product Service GmbH, Notified Body Number 0123, Certificate No. V1 03 11 40885 003.

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

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

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

12/2/2003