



## EC Declaration of Conformity

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

Product Names: **QuickVue® H. pylori gII™ Test (Catalog #0W009)**

Description: **The QuickVue H. pylori gII test is intended for the rapid, qualitative detection of IgG antibodies specific to *Helicobacter pylori* as an aid in the diagnosis of *H. pylori* infection.**

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: **December 2, 2003**

QUIDEL Corporation, being the manufacturer / distributor within the European Economic Area hereby declares that the products covered by the declaration conform to 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: \_\_\_\_\_

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

12/2/2003

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