



EC Declaration of Conformity

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

Product Names: QuickVue® H. pylori gII™ Test (Catalog #0W009, #0W010, and #20101)

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.

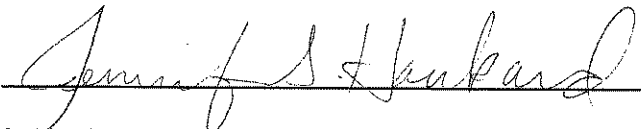
Classification: General In Vitro Diagnostic Device

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

Estimated Start of CE-Marking: March 4, 2005

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: 3/4/05

Jennifer S. Hankard
Regulatory Affairs Manager
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