



EC Declaration of Conformity

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

Product Names: QuickVue®+ One-Step hCG Combo Test (Catalog #00178 and #00179)

Description: The QuickVue One-Step hCG Combo test is intended for the qualitative detection of human Chorionic Gonadotropin (hCG) in serum or urine for the early detection of pregnancy.

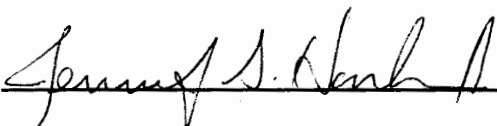
Classification: General In Vitro Diagnostic Device

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

Estimated Start of CE-Marking: November 20, 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: 11/20/2003

Jennifer S. Hankard
Regulatory Affairs Manager
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