



EC Declaration of Conformity

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

Product Names: QuickVue® Dipstick Strep A (Catalog #20108, #20125, #20163)

Description: The QuickVue Dipstick Strep A test is intended for the rapid, qualitative detection of Group A Streptococcal antigen directly from patient throat swab specimens as an aid in the diagnosis of Group A Streptococcal 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: November 26, 2001 (#20125)
April 27, 2004 (#20108)
July 9, 2004 (#20163)

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

Date: 7/9/2004

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