



EC Declaration of Conformity

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

Product Names: Sofia™ Analyzer and Sofia Influenza A+B FIA (Catalog #20221, 20230, 20218)

Description: The Sofia Influenza A+B FIA employs immunofluorescence to detect influenza A and influenza B viral antigens in nasal swab, nasopharyngeal swab, and nasopharyngeal aspirate/wash specimens taken directly from symptomatic patients. This qualitative test is intended for use as an aid in the rapid differential diagnosis of acute influenza A and influenza B viral infections. The test is not intended to detect influenza C antigens. A negative test is presumptive and it is recommended these results be confirmed by cell culture. Negative results do not preclude influenza virus infections and should not be used as the sole basis for treatment or other management decisions. The test is intended for professional and laboratory use.

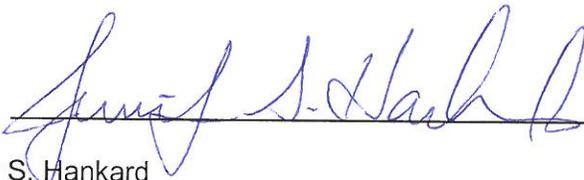
Classification: General *In Vitro* Diagnostic Device

Conformity Assessment Route: Annex III of Council Directive 98/79/EC Concerning *In Vitro* Diagnostic Devices.

Estimated Start of CE-Marking: October 1, 2011

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: 

Date: 8/1/2011

Jennifer S. Hankard
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