QUIDEL
CORPORATION

EC Declaration of Conformity

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

Product Names: **Sofia® Analyzer (Catalog #20221 and #20221R)**
Sofia RSV FIA (Catalog #20242 and 20260)
Sofia Installation Pack (Catalog #20230)

Description: **The Sofia RSV FIA employs immunofluorescence for detection of respiratory syncytial virus (RSV) nucleoprotein antigen directly from nasopharyngeal swab and nasopharyngeal aspirate/wash specimens from symptomatic patients. This qualitative test is intended for use as an aid in the rapid diagnosis of acute RSV infections. Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or other management decisions.**

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 for Sofia RSV FIA: **September 14, 2012**

Authorized Representative: **MDSS GmbH**
Schiffgraben 41
30175 Hannover, Germany

Quidel Corporation, being the manufacturer, hereby declares that the products covered by this 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: Jennifer S. Rial Date: 2/4/2014

Jennifer S. Rial
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