

## DECLARATION OF CONFORMITY

**Manufacturer:** Quidel Corporation  
Specialty Products Group  
2981 Copper Road  
Santa Clara, California 95051  
USA

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

**Product Name:** MicroVue™ SC5b-9 Plus Enzyme Immunoassay

**Description:** The MicroVue SC5b-9 Plus Enzyme Immunoassay measures the amount of the SC5b-9 complex present in human plasma or serum specimens, as well as in other biological fluids or experimental samples.

**Classification:** Article 9, paragraph 1 of EC Council Directive 98/79/EC on *In Vitro* Diagnostic Devices

**Conformity Assessment Route:** Annex III (IVDD)

**Estimated Start of CE-Marking:** April 11, 2007

Quidel Corporation, being the manufacturer 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. Supporting documentation is retained under the premises of the manufacturer.

Signed Rebecca Ramirez

Date 11/9/09

Rebecca Ramirez  
QA/RA Analyst  
Quidel Corporation  
Specialty Products Group  
2981 Copper Road  
Santa Clara, CA 95051  
USA